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**Conference of Radiation Control
Program Directors, Inc.**

ORIGINAL

11th Annual
NATIONAL CONFERENCE ON RADIATION CONTROL

Radiation:
Minimizing Exposure; Optimizing Use

May 6-10, 1979

Oklahoma City, Oklahoma

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June 1981

Cosponsored by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

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ENVIRONMENTAL PROTECTION AGENCY
Office of Radiation Programs

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U.S. NUCLEAR REGULATORY COMMISSION

and

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

Bureau of Radiological Health
Rockville, Maryland 20857

I

FOREWORD

The Bureau of Radiological Health develops and carries out a national program to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiations and to ensure the safe, efficacious use of such radiations. The Bureau publishes the results of its work in scientific journals and in its own technical reports.

These reports provide a mechanism for disseminating results of Bureau and contractor projects. They are distributed to Federal, State, and local governments; industry; hospitals; the medical profession; educators; researchers; libraries; professional and trade organizations; the press; and others. The reports are sold by the Government Printing Office and/or the National Technical Information Service.

The Bureau also makes its technical reports available to the World Health Organization. Under a memorandum of agreement between WHO and the Department of Health and Human Services, three WHO Collaborating Centers have been established within the Bureau of Radiological Health, FDA:

WHO Collaborating Center for Standardization of Protection Against Nonionizing Radiations;

WHO Collaborating Center for Training and General Tasks in Radiation Medicine; and

WHO Collaborating Center for Nuclear Medicine.

Please report errors or omissions to the Bureau. Your comments and requests for further information are also encouraged.

John C. Villforth
Director
Bureau of Radiological Health

CONTENTS

Page

FOREWORD ii

ABSTRACT ix

OPENING SESSION, SUNDAY, MAY 6, 1979
Moderator: *Alice Dolezal* 1

Welcome from the State of Oklahoma
J. Dale McHard 2

Highlights of the CRCPD Activities
Alice Dolezal 3

The Healing Arts Council Report
Gerald W. Allen 6

The Environmental and Nuclear Council Report
Heyward Shealy 7

Keynote Address: Radiation--How Low Should/Can We Go?
Norman Hilberry 10

Report on Current and Projected Federal Radiation Protection Activities
William A. Mills, Robert G. Ryan, and James S. Benson 20

GENERAL SESSION: LOW LEVEL RADIATION, MONDAY, MAY 7, 1979
Moderator: *Thomas M. Gerusky* 31

Perspective from BEIR Report, 1979
Albert W. Hilberg 33

ALARA -- Radiation Risks and the Need to Keep Exposures "As Low as Reasonably Achievable"
Allen Brodsky 38

Findings and Recommendations of the Interagency Task Force on Radiation Exposure
Kathleen Blackburn 49

Development of Radiation Protection Guidance for Occupational Exposures
Luis F. Garcia 57

NRDC's Position on Low-Level Radiation Exposure
Arthur Tamplin 65

GENERAL SESSION: MEDICAL RADIATION ISSUES

SESSION: Regulations - Pain or Panacea
Moderator: *Alice Dolezal*

Regulations Impact on Radiology
Otha W. Linton 71

Page

Radiation Control Regulations are Necessary and Effective
Marshall W. Parrott and Darrell L. Hocken. 75

Planning Regulations can Complicate your Life
Jerome H. Shapiro. 78

The Impact of Regulations on the Hospital Physicist
William R. Hendee. 83

Cost/Benefit of the Diagnostic X-Ray Standard--A Second Look
R. Phillips, H. Rudolph, and T. Shope. 87

SESSION: Referral Criteria for Medical Radiation Procedures
Moderator: *Jerome H. Shapiro*

What Should/Shouldn't the Radiologist be Asked to do?
William E. Jobe. 95

Why the Physician Needs an X-Ray
Mark Johnson 98

Referral Criteria--The Unmet Need to Optimize Radiation Use
Mark Barnett, James L. Morrison, and William S. Properzic. 102

Third-Party Role in Referral Criteria
W. Fred Lucas. 106

State Role in Better Utilization of X-Ray Technology
Jane R. Fisher 110

CONCURRENT SESSION A: ULTRASOUND - "THE STATE-OF-THE-ART," TUESDAY, MAY 8, 1979
Moderator: *David K. Lacker.* 113

What do we Know About the Bioeffects?
Melvin L. Stratmeyer 114

Ultrasound Diagnostic Equipment and Its Use
Ross E. Brown. 121

Ultrasound Potential and New Applications in Medicine
Marc S. Lapayowker 127

Diagnostic Ultrasound Output Levels and Quality Assurance Measurement Techniques
Harold F. Stewart. 131

The BRH Proposed Action Program for Diagnostic Ultrasound Equipment
Robert G. Britain. 147

CONCURRENT SESSION B-1: WASTE MANAGEMENT
Moderator: *E. Frank Wilson*

The Administration's Plan for Radioactive Waste Management
Goetz K.H. Oertel. 150

State Response to the Federal Program for Radioactive Waste Management
Charles M. Hardin. 158

Page

CONCURRENT SESSION B-2: TRANSPORTATION OF RADIOACTIVE MATERIALS
Moderator: *J. Dale McHard*

Panel on State Notification
E. Frank Wilson and Aubrey Godwin 163

Federal-State Relations in the Transportation of Radioactive Materials
Lee Santman 169

State Surveillance of Radioactive Material in Transport - Georgia
Andrejs Simanis 175

GAO Report on the Transportation of Radioactive Materials
Michael Gryszkowiec 177

CONCURRENT SESSION C: OPTIMIZING RADIATION USE, WEDNESDAY, MAY 9, 1979
Moderator: *Gerald W. Allen* 183

Nuclear Medicine-Quality Assurance Programs
Arthur B. McIntyre 185

AAPM's Quality Assurance Activities
Robert G. Waggener 187

Quality Rating of Diagnostic X-Ray Facilities
Charles M. Hardin 190

A State's Involvement in Quality Assurance
Maury Neuweg 196

Quality Assurance in an Uncontrolled State: NEXT and BENT in Iowa
Roger W. Cochran 199

The Use of QA Activities in lieu of a Regulatory Hammer
Edd Johnson 204

NEXT/DENT Comparison Study
Fred G. Rueter and George H. Koustenis 206

Use of BENT in Oklahoma
William M. Kemp 218

Patient Exposure Reduction by "Limits"
Dale E. Gergely 222

Patient Exposure in Chest Radiography
Richard E. Gross 230

It's Time to Talk about RED (Radiation Experience Data)
William S. Properzio 237

CONCURRENT SESSION D: RADIOACTIVITY CONTAMINATION PROBLEMS AND NATURAL AND ACCELERATOR PRODUCED RADIOACTIVE MATERIALS
Moderator: *Heyward G. Shealy*

NARM Overview
Edgar D. Bailey 239

BEST DOCUMENT AVAILABLE

Page

NORM Overview
L. Hall Bohlinger 243

Radiologic Aspects of Zircon Sands
David G. Wagstaff 246

Field Surveys of Phosphate Slag Use in Soda Springs, Idaho
Bruce H. Peterson 250

NORM Studies in the State of Washington
Ellen G. Haars 259

Radium Removal from Water
Lewis M. Cook 262

Status of Current Studies of Radon in Public and Private Water Supplies in New England
Wallace W. Hinckley 266

Radioactivity Associated with Selected Mineral Extraction Industries
Donald W. Hendricks and Vernon E. Andrews 270

The Role of the Bureau of Radiological Health in NARM Evaluation
Allan C. Tapert 276

The CONDOS Methodology for Evaluation of Radiation Exposure from Consumer Products
F. R. O'Donnell 280

Licensing for State Control of NARM
Paul D. Eastvold 289

CONCURRENT SESSION E-1: LASERS, THURSDAY, MAY 10, 1979
Moderator: *Lawrence J. McDonnell* 295

Use and Misuse of Lasers in Medical Practice
Herbert T. Wood, Gregory B. Talley, and Norman J. Stewart 297

Another Look at Laser Light Shows - BRH Enforcement Activity
Robert T. Handren 299

Evaluation of Laser Light Show Hazards
Jerome E. Dennis, James E. Frye, and John J. Galli 303

The Model State Safety Regulations for Lasers
Jack C. Rogers 308

CONCURRENT SESSION E-2: CREDENTIALING
Moderator: *John R. Stanton*

Federal Activities in Operator Credentialing
Polly C. Story 310

Credentialing: The "Nitty-Gritty" of Implementation
Donald R. Hughes 312

Proposed Regulations for Qualifications of Licensed Users of Radioactive Materials
H. Ellis Simmons 316

Recommendations of the Credentialing Task Force for Allied Health Operators
Joseph M. Nanus 319

CONCURRENT SESSION F-1
Moderator: *Eddie S. Fuente*

How to Use the NARM Guides
Edgar D. Bailey 326

Licensing State Concept - How it would be Implemented
Albert J. Hazle 330

The Discovery and Assessment of Former Radium Processing Sites
Albert J. Hazle 333

Biological Indicators as an Aid in Dose Estimation
Francis J. Bradley and Niel Wald 336

CONCURRENT SESSION F-2
Moderator: *Ted Wolff*

Reporting of Environmental Radiation Measurement Data
R. Colle 342

Oklahoma TLD
Rita S. Patel, Donald J. Burke, and Robert L. Craig 359

Study of the Long-Term Effects in the Beagle from Whole Body Exposure to Ionizing Radiation-Current Findings
S.A. Benjamin, G.M. Angleton, A.M. Hargis, R.S. Jaenke, A.C. Lee, C.W. Miller, R.W. Norrdin, and R.D. Phemister 365

PLENARY SESSION
Moderator: *Alice Dolezal*

Is There an Environmental Radiofrequency Radiation Problem?
David E. Janes 376

FDA's Proposed Protective Action Guides for Food, Milk, and Thyroid-Blocking
Bernard Shleien 390

The "Truth" About Three Mile Island, Harrisburg, Pennsylvania and the Impact on Radiation Protection Agencies
Thomas M. Gerusky, Robert G. Ryan, Bernard Shleien, and Floyd L. Galpin 396

Closing
David Lacker, Robertson J. Augustine, Sheldon A. Schwartz, and James W. Miller 418

ABSTRACT

This publication contains the proceedings of the Eleventh Annual National Conference on Radiation Control--Radiation: Minimizing Exposure; Optimizing Use, held May 6-10, 1979, in Oklahoma City, Oklahoma. Sponsors were the Conference of Radiation Control Program Directors, Inc.; the Bureau of Radiological Health, FDA; the U.S. Environmental Protection Agency; and the U.S. Nuclear Regulatory Commission. Participants representing State and major local radiation control programs, as well as Federal agencies, discussed mutual radiation control programs. The formal presentations are included in these proceedings.

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OPENING SESSION

Moderator: *Alice Dolezal*, Minnesota

WELCOME FROM THE STATE OF OKLAHOMA
J. Dale McHard, Chief, Occupational and Radiological Health Service, Oklahoma Department of Health

HIGHLIGHTS OF THE CRCPD ACTIVITIES
Alice Dolezal, Chairman, Conference of Radiation Control Program Directors, Inc.

THE HEALING ARTS COUNCIL REPORT
Gerald W. Allen, Director, Division of Environment, Kansas Department of Health and Environment

THE ENVIRONMENTAL AND NUCLEAR COUNCIL REPORT
Heyward Shealy, Chairman, Chief, Bureau of Radiological Health, South Carolina Department of Health and Environmental Control

KEYNOTE ADDRESS: RADIATION--HOW LOW SHOULD/CAN WE GO?
Norman Hilberry, Department of Nuclear Engineering, University of Arizona, Tuscon, Arizona

REPORT ON CURRENT AND PROJECTED FEDERAL RADIATION PROTECTION ACTIVITIES
William A. Mills, Acting Deputy Assistant Administrator for Radiation Programs, U.S. Environmental Protection Agency
Robert G. Ryan, Director, Office of State Programs, U.S. Nuclear Regulatory Commission
James S. Benson, Deputy Director, Bureau of Radiological Health, Food and Drug Administration

WELCOME from the STATE of OKLAHOMA

J. Dale McHard
Chief, Occupational and Radiological Health Service
Oklahoma Department of Health

On behalf of the Governor of the great State of Oklahoma, the Honorable George Nigh, and the 2.8 million friendly citizens of Oklahoma, I bid you welcome.

I think from the folder that you have been given, you can see that we are celebrating here in Oklahoma the Will Rogers Centennial, the 100th anniversary of his birth. As you all know, Will Rogers is one of the most honored and respected native sons of Oklahoma. He was well known before his death as a raconteur, a columnist, an observer of the political scene in particular, and of life in general. Perhaps one thing that he was very famous for was his ability to sublime his observations down into very short statements. That will be the context of my welcoming speech; a very short statement.

Will Rogers did say one thing that I want to refer to in welcoming you to Oklahoma. He said "I never met a man I didn't like." I think that it is appropriate to call forth this statement today because it exemplifies perhaps more than any other statement that I could bring up, the friendly, relaxed atmosphere which is the spirit of the hospitality of Oklahoma.

On a more personal basis, I would like to say that it is a pure joy and indeed a very great pleasure for me to stand here on the dais and look out and see friends and colleagues who have chosen this field of radiation control. For myself, I would simply say "welcome to Oklahoma, my native land."

Please feel free to call upon me if I can be of any assistance to you while you are here at the meeting. If there is anything that we, the local hosts, can do to make this meeting a more successful meeting in any way, please feel free to call on us. I do feel that we will have a very successful and informative meeting.

In conclusion then, simply let me say "howdy; welcome; I'm glad y'all came."

HIGHLIGHTS of the CRCPD ACTIVITIES

Alice Dolezal
Chairman
Conference of Radiation Control Program Directors, Inc.

The organization of the annual meeting is always a major task for the Conference Executive Board and the local hosts. I want to express my gratitude for the efforts of our hosts Dale McHard, Bob Craig, and their staff for our local arrangements. Our thanks go also to the regional representatives of the Federal agencies; Dr. James McTaggart, FDA, and his staff; and Henry May, EPA, for their assistance. Special recognition must also be given to Dr. Jim Miller of BRH, Dr. Bob Augustine of EPA, Shelly Schwartz of NRC, and Elmer Eisenhower of NBS who so ably and successfully responded to their responsible roles of liaison with the Conference. Thanks also to Marie Janinek of NRC, who assisted Shelly, and Lois Miller, formerly with EDRO.

The Conference has had an active and productive year. The fruits are being reaped from not only this year's but also previous years' work by Conference members. The number of Conference associate members grows as the staff of Radiation Control programs join the Conference. We welcome all the new members to this meeting as well as all the members who have worked with the Conference for years. We remember at this time two Conference members who passed away this year; Bill Horton of Nevada and Martin C. Wukash of Texas. They are missed. We welcome too all the Federal representatives and the other participants to this meeting.

The activities of the Conference have been varied this year. The voice of the Conference was heard at Congressional hearings as well as meetings of the National Governors Association, IRG Task Force on Nuclear Waste Management and advisory meetings to Federal agencies. The Senate Committee on Commerce, Science, and Transportation mentioned the Conference by name in its "Report on Radiation Health and Safety" when it recommended that the National Bureau of Standards work with the Conference to establish the need for intermediate or regional calibration centers. Task Force No. 16 on Radiation Measurements is working with NBS to fulfill the recommendation by identifying the needs and suggesting mechanisms by which radiation measurements might be improved. A great deal of effort has been devoted to this enterprise. You will be hearing much more about implementing the project in the coming years.

The Conference has devoted considerable time this year to the problem of nuclear waste disposal. Heyward Shealy, as Conference representative, presented testimony on this subject last July to the Senate Committee on Governmental Affairs, Subcommittee on Energy, Nuclear Proliferation and Federal Services. The Conference was also represented at the IRG Nuclear Waste Management Committee meeting in preparation for presenting the report to the President. The Department of Energy has been very helpful to Task Force No. 8 on Nuclear Waste as it has been wrestling with proposed Federal rules and current problems in nuclear waste. The Conference Executive Board met with the Department of Energy and had several telephone contacts to determine the procedure by which the Department of Energy will contract with the Conference. The Executive Board will discuss this further with the Department of Energy representative during the meeting this week. We look forward to working closely with this Agency.

A problem that surfaced periodically this year was transportation. On November 29, 1978, Jim Porter represented the Conference at the Department of Transportation Public Hearing on Highway Routing of Radioactive Materials. We will be devoting time to the issue of transportation of radioactive materials in future years. Because this issue plays an important part in all of our programs, we are attempting to establish a formal liaison with the Department of Transportation. We feel that direct lines of communication with the Agency could be as mutually beneficial as they have been with the other Federal agencies with whom we have formal communication. We are fortunate in having a representative of the Department address us during this meeting. The Execuitve Board will meet with him to discuss further a liaison relationship. We look forward to this discussion.

An area that will affect many States, both Agreement and non-Agreement is P.L. 95-605, the Uranium Mill Tailings Radiation Control Act of 1978. Conference members have received copies of the law and a short discussion of the Conference's concerns with some provisions in the law. An Ad Hoc Task Force was formed to evaluate this bill. The Conference has expressed its concerns to the Nuclear Regulatory Commission Chairman, as well as to the Senate Committee who proposed the bill. We have not yet heard from these groups. Items such as the implementation date of November 1978 not allowing adequate time for States to prepare for the requirements, the necessity for Agreement States to renegotiate their agreements with NRC, and dual regulatory jurisdiction are of real concern to States.

The long awaited 1978 edition of the Suggested States Regulations has been published. We recognize the extensive work that Conference members, Federal resource persons, consultants, users, and public members have devoted to this endeavor. Each section and subsection has been reviewed by literally hundreds of organizations, agencies, consultants, and users. The SSRCR is utilized by many States in writing regulations. To keep the Suggested State Regulations viable and current with changing technology and Federal regulation, the Executive Board has voted to permit revision of sections or portions of sections between complete SSRCR revisions every 4 years. Regulations and the need for regulations are frequently controversial. The topic will be pursued tomorrow in several presentations and discussions.

The 19 Conference Task Forces have begun functioning on the calendar year, so the annual task force reports are not due until December. However, progress reports are to be submitted after each meeting. The Healing Arts and Environmental Nuclear Councils have been providing guidance to the task forces. The Councils report to the Executive Board at its meetings. Jerry Allen and Heyward Shealy will give presentations on activities of the Councils and Task Forces later this afternoon.

The Task Force on Communication and Training reports directly to the Executive Board rather than through the Councils. The charge to Task Force No. 10 was expanded this year to include developing an inventory of training resources in radiological health within each State and a mechanism for communicating the list of resources to all State and sponsoring Federal Agencies. Through the resources identified training needs for the States may be satisfied as State programs are able to utilize the resources. Although there has been some use of the Bureau's T.V. National Radiation Control Network this past year, the potential for utilizing the system for training has barely been tapped.

Another phase of the charge given to Task Force No. 10 is to provide assistance to Federal Agencies in evaluation of appropriate communication with consumers regarding radiation safety of consumer products containing radionuclides. This is an essential area of communication and public education that requires considerable coordination.

One of the "buzz words" these days is "efficacy." Although the term can be applied to many areas, it is often used in discussing medical radiological practices. Numerous studies have been conducted on some phase of the topics. But, like a mosaic, the parts of the picture are still being fitted together to get a comprehensive view. Recognizing the importance of efficacy, the Conference gave Task Force No. 18 the charge to explore the feasbilility of establishing a data base to evaluate efficacy of medical radiological practices in the healing arts. The Task Force was further charged to define the role of radiation control agencies in a national program to improve efficacy of radiation. The theme of this annual meeting "Radiation: Minimizing Exposure; Optimizing Use" is a simplified way of

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ous use of radiation. Determining efficacious use and measuring it is a be pursued in the coming years.

activity of meetings, contacts, and communications the Conference has arer identity. Last year at the annual meeting the Conference was elop "clout." This term has become a popular word so I turned to the Webster's meaning. The archaic use of clout was to indicate a piece of r patching. The slang meaning of clout is a long, powerful hit in baseball. oquial definition of the word is a blow, as with the hand.

of the definitions appears to have a direct applicaton to the Conference, defined object or action to produce results is indicated. The Conference becoming more clearly identified as it reaches maturity. Through the the Conference members various Congressional committees as well as have heard the message from the States. Many Conference actions have n assisting States' radiation control programs and providing guidance for sources.

lous force. It is not something you can grasp in your hand. Rather it is a hieving your goals.

pate in the meeting this next week keep in mind the tools you have to exposure and optimize its uses.

The HEALING ARTS COUNCIL REPORT

Gerald W. Allen, Chairperson
Director, Division of Environment
Kansas Department of Health and Environment

I am pleased and embarrassed as I stand before you today. Pleased because of the opportunity this provides for me to credit those special people - the Task Force Chairpersons who make the task forces work; pleased because of the very real progress several task forces have made toward accomplishing goals established by the Conference; pleased because the Healing Arts Council can see from its unique position just what kinds of effort must be made by very busy people to accomplish such tasks and can give deserved public credit for that effort.

I am embarrassed because I, as Chairperson of the Healing Arts Council, could not accomplish the full operation of that council in the manner hoped. Our meetings have, by necessity and probably Chairperson inattention, been limited to telephone meetings. We have only just begun to communicate as we should have been all along and we have yet to attack some major problems.

What follows is a task force by task force accounting of the work done in calendar year 1978. Because work is already underway in 1979, there will be some overlap, but essentially this is the 1978 accomplishment.

Task Force No. 2A - Was chaired by Edd Johnson of Wyoming with Warren Jacobi of Colorado, and Ernest Ranieri of Idaho; John Shaver was consultant; BRH resource person was Richard Gross; EPA resource person was Dr. DeVaughn Nelson; and Region VII resource person was Bobby Dillard.

During 1978, this task force produced a draft of criteria for State x-ray program adequacy using as a starting point a document produced for the Seattle meeting and 22 comments from 19 separate State programs on that document. A new report has been produced. The calendar year 1979 efforts to complete the document have resulted in a meeting being authorized to finalize the product. Draft copies have been reviewed and the content appears excellent. The task force has also identified at least two other related issues, which were discussed with the Executive Board yesterday.

Task Force No. 3 - Efficacy - During calendar year 1978, Task Force No. 3 met twice and its Chairperson, Jerry Parker of Massachusetts, reports that a questionnaire was designed and sent to all Conference members. It is hoped this will provide data that will indicate which States require x-ray procedures that have a low yield. A list of medical schools presenting courses on radiation protection will be provided in the coming year's report. Task Force members Jan Fisher, Pennsylvania, and Charles Hardin, Kentucky, attended the National Conference on Referral Criteria for X-Ray Examinations, HEW, Washington, D.C., October 25 - 27, where the issues of patient referral criteria and defensive radiology were explored. It appears this task force has now acquired the background and is acquiring the data to produce a plan for developing good patient selection criteria and of promoting the value of using such criteria. The Federal personnel associated with this task force are: BRH - James L. Morrison; EPA - Dr. DeVaughn Nelson; and Region I -Robert Hallisey.

Task Force No. 4 - NEXT - Chaired by Beattie L. DeBord of West Virginia, with Phillip Babb, Kentucky; Kenneth Miller, Missouri; John Stanton, New Hampshire; BRH resource person, Fred C. Reuter; EPA resource person, Dr. DeVaughn Nelson; and Region III resource person, Henry Kocol.

The ENVIRONMENTAL and NUCLEAR COUNCIL REPORT

Heyward Shealy, Chairman
Chief, Bureau of Radiological Health
South Carolina Department of Health and Environmental Control

Council Members: Aubrey Godwin, Alabama
Larry McDonnel, Wisconsin

Task Force No. 1 (NARM). Task Force on Evaluation and Distribution of Radioactive Sources and Devices not Manufactured under the Atomic Energy Act; Ed Bailey, Chairman.

Many radioactive products not manufactured under the Atomic Energy Act have been identified, and an evaluation of these products in some 11 States is now in the process of being done. This Task Force has formulated guides to assist States in evaluating and licensing these products. The last two guides are listed as guide 13 (Standard (NARM) Licensing Conditions) and guide 14 (On-Site Surveys of Manufacturer, Assemblers, and Distributors of NARM Products). Guides will continue to be updated as appropriate.

Task Force No. 7. Task Force on Natural Radioactivity Contamination Problems; Hall Bohlinger, Chairman.

During the Wednesday morning session, Ed Bailey and Hall Bohlinger will present an overview of these two task forces.

This Task Force is scoping the problem of contamination by natural radioactivity. States have been asked to identify problem areas; mining, processing, or manufacturing activities that are being done in their respective States. Dose pathways are now being addressed as they pertain to the specific areas identified.

Task Force No. 8. Radioactive Waste Management; Ted Wolff, Chairman.

During 1978, the Task Force prepared and presented testimony before the Senate Subcommittee on Energy and Nuclear Proliferation. One of the projects of this Task Force for 1979 will be a report on "Environmental Monitoring around Radioactive Waste Disposal Facilities."

The Task Force has also commented on NUREG-0456 entitled "A Classification System for Radioactive Waste Disposal - What Waste Goes Where," and prepared Conference response to U.S. Department of Energy report entitled "Draft Report to the President by the Interagency Review Group on Nuclear Waste Management."

Task Force No. 9. A Task Force to Establish Soil Contamination Limits; Al Hazle, Chairman.

This Task Force is now assisting Federal agencies in scoping the problems of soil contamination and identifying the need for contamination limits to be established.

1. The NEXT Handout Brochure to be left at the facility .
2. DENT/NEXT intercomparisons of data.
3. New projections were suggested including lateral chest and hip pinning.
4. Exposure guidelines were discussed, and it was suggested that Task Force No. 13, Quality Assurance, might be able to assist.

By October, the task force was recommending inclusion of lateral chest and hip pinning and the development of chest, abdomen and skull phototimed measurements. Finally, a joint meeting with QA was scheduled for calendar year 1979.

Task Force No. 5 - Credentialing of Allied Health Radiation Operators - Produced a draft minimum standard for diagnostic radiologic technologists. The document has been distributed for comments. Joseph M. Nanus of Texas, the chairman of this task force, and the entire group, including Raymond McCandless, Vermont; Ellis Simmons, Nebraska; Donald Hughs, Kentucky; Dennis Hahn, Michigan; Wayne Carlson and Polly Story, BRH resource persons; Dr. Nelson of EPA, with able assistance from Bobby Dillard of Region VIII, must have all worked hard to produce the document now in the final stages of completion. It is this Task Force Chairperson that I must especially note because of his suggestions, comments and attention to detail. Joe's task force always got the letter from me with the error, Joe always found it and, to his credit, he never lost patience with me or even made me feel the embarrasment due for the errors made. Publicly then, Joe, thank you for your patience and please stick with me; I'll get it right yet.

Task Force No. 11 - Public Health Impact of Nuclear Medicine - Spent calendar year 1978 looking for organization and leaders. I believe that problems may now be solved and we can expect good work in 1979.

Task Force No. 14 - Quality Assurance in Diagnostic X-Ray - Produced a draft document in calendar year 1978, collected and reviewed comments, and began the process of finalizing the document. Chairperson Maury Neuweg of Illinois reported that 24 States commented. The revised draft is expected soon and already in 1979 the NEXT and QA Task Forces have begun their joint consideration of exposure limits or guides. The Task Force members, Eugene Fisher, New Jersey; Robert Craig, Oklahoma; and the resource persons Richard Gross, BRH; De Vaughn Nelson, EPA, and James Kraeger, Region V, are to be congratulated on their work in 1978 and the new members, Diane Tefft of New Hampshire and Michael Odlaug of Washington, should be warned that this task force makes things happen.

Task Force No. 15 - Mammography - Was retained; although, at the request of the Conference, it held no meetings since the last Conference meeting.

The Healing Arts Council - Has, over the calendar year 1978, made many starts, a few mistakes, and several successes. We have already sent each Chairperson a document showing the changes (both general and specific), the membership, the number of meetings expected, and a document the Board developed, which outlines the actual policy and procedures (rather like an operations manual) for Task Force Chairpersons.

One of our major goals in 1979 will be improved communication with Task Force Chairpersons and the Board. Indeed, we are now actively seeking guidance from them or any other Conference members on changes to charges, better methods of communication, new issues to attack. I am convinced after my first year as Healing Arts Council Chairperson that, given a properly outlined task, these people can do it; even given no task outline or a vague one, these are people who can accomplish the task.

Task Force No. 12. Emergency Response Planning; Dave Snellings, Chairman.

Representatives from different national organizations are now meeting and discussing together radiological emergency response planning for fixed nuclear facilities. Emergency Planning will very likely take on new dimensions since the TMI incident.

This organization is called the Interorganizational Committee on Radiological Emergency Response Planning and Preparedness (IOAC). Members of this organization consist of Conference of Radiation Control Program Directors, the U.S. Civil Defense Council (USCDC), and the National Association of State Directors for Disaster Preparedness (NASDDP). NUREG-0396 and PAZ have been discussed quite extensively by this group. The group is also actively involved in reviewing FDA's recently published PAG's for the radioactive contamination of human food and animal feeds, and potassium iodide thyroid blocking guidelines.

Task Force No. 15. Personnel Dosimetry; Larry Lloyd, Chairman.

Very interesting information is being generated by this Task Force on the reliability of processors of personnel dosimeters. This information is being reflected in the NRC contracted pilot study on personnel dosimeter performance conducted by the University of Michigan.

In conclusion, I hope this has given you some idea of the scope of these task forces in environmental and nuclear issues. I personally feel task force activity in the environmental and nuclear area will increase in the future as new Federal laws are implemented and more attention focused on nuclear power issues.

KEYNOTE ADDRESS

RADIATION--HOW LOW SHOULD/CAN WE GO?

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Frankly, I have been unable to figure out why I have been asked to give the keynote talk here this afternoon. I certainly am neither sufficiently noted nor, I hope, sufficiently notorious to serve as a drawing card. I have no high government connections that would enable me to provide you with predictions as to the probable future welfare of either our research or our regulatory programs. And one scan of your program makes it very clear that I am in no way qualified to provide a highlights review of the present status in all of the areas of activity involved in the regulatory control of radiation exposures. This an active leader in the field could do and thus give a major "off-the-marks" impulse to the conference proceedings.

I thought briefly that perhaps I was the Program Committee's obeisance to the "full public participation" syndrome. I had to rule that out because I have been closely involved with the radiation field in one way or another for 40 years, so that I could hardly be classified as a truly lay member of the public. From 1939 to 1942, I chased cosmic rays in the Rocky Mountains up to an altitude of some 13,200 feet and then in the Andes to 19,200 feet. This was back when one had to make his own Geiger tubes and his own electronic circuitry. Then in 1942 I was asked by Dr. Arthur Compton, Director of the Metallurgical Project section of the overall OSRD-Manhattan District Atomic Bomb Project, to serve as his aide, which I did throughout the war years. As such, I was involved in setting up the project's personnel radiation monitoring program, in organizing a project division to design and see to the production of the needed monitoring instruments and then in establishing the radiobiology research program, the uranium and exotic materials toxicology studies, the medical research program, and the clinical radiation exposure surveillance system.

At the end of the war, I stayed with the project, which was now named Argonne National Laboratory and operated by the University of Chicago for the U.S. Atomic Energy Commission. My responsibilities in the laboratory director's office included the continuing cognizance of the research programs in radiobiology, in radiological physics, and in medicine as well as oversight of the health physics monitoring program and the closely coupled emergency procedures planning and practices.

Then, 15 years ago I retired and have served as professor of nuclear engineering at the University of Arizona ever since. My principal duties have been teaching our departmental freshmen, with a sprinkling of students from all across the campus, in our Introduction to Nuclear Engineering course. This student contact does provide an effective line of contact with the lay public as well, because the students come in with all of the questions and arguments that they are confronted with. The professor of nuclear engineering post opens another line of communication with the public through the constant flow of requests to talk to service clubs, citizens groups, religious groups, schools, and so forth. The inevitable question and answer periods, when summed over all the various interest and background types, give a fair profile of the public interest and of the public concern.

In addition to my university position I have also served for the past 10 years as a member of the State of Arizona Atomic Energy Commission. This has enabled me to keep my hand in, as it were, in the radiation regulatory business.

While my experience in handling the public relations affairs for the laboratory and the ensuing 15 years as a university professor certainly do not qualify me as a representative of the public, it might suggest some approaches to public participation activities that would prove useful in the days of regulatory controversy that we are already experiencing and that promise to continue for at least the immediate future. One thing that that experience makes very clear is that the truly serious problems we face are not scientific or technological. Our real problems are people problems and they are indeed serious. The sooner we begin really to believe this and to tackle the situation we face from this point of view, the better off we are going to be.

This is the career background which inevitably provides an element of bias to whatever I have to say. I am strongly in favor of the use of radiation and of radioactive isotopes in all facets of technology. I am convinced that we have only begun to tap the potentials that they are capable of providing to humankind. At the same time I am acutely conscious of health problems involved in their use. I am also convinced of the need for strict control of radiation exposure whether from external sources or from internal emitters and therefore for fully effective systems for radiation monitoring of locations of use and of their immediate neighborhoods which would be subject to overexposure should there be accidental radioactive releases. I subscribe to the philosophy that all radiation exposures should be as low as reasonably possible. I recognize, however, that the crucial difficulty with this statement lies in the definition of "reasonable." I believe, nevertheless, that it is possible to implement the first half of the theme of this conference, "Minimizing Exposure," and at the same time accomplish the second half, "Optimizing Use."

I must apologize for this lengthy preamble. I have found, however, in dealing with the public in these days when every speaker's credibility is in question, that it pays to lay out all the background cards on the table face up. The listener then feels that he can evaluate what you say, whether he agrees with it or not.

The function of the keynote speaker as I see it is to set the stage, as it were, for the conference action. That means to establish the background against which the conference action will be carried on and perhaps to add some touches to the stage setting itself as it has been set by the program committee by its development of the conference program. The most the speaker can do in this latter case is to suggest a lighting chart which would in its turn provide a pattern of emphasis to be followed in the various phases of the program's presentation.

The key consideration in determining a proper stage setting and lighting chart is the character of the audience to be addressed and the nature of its mood. For the present conference I believe there are, or at least should be, three such audiences.

The one audience is the group of us assembled in this room. We know each other, we have a common background, we talk the same language, we have the same general perspective on life and our times. We have problems; we know pretty well what they are and we can discuss amongst ourselves how they should be handled. By and large we are likely to be an objective group, and the word reason still has meaning as far as most of us are concerned. But we are really only a small part of the audience to which the proceedings of this conference are of concern. A second audience is comprised of the whole community of those engaged in the study of radiation and radioactive substances and in their monitoring and control. This includes an important segment of the scientific community, a growing component of industry, an important division of the medical profession, and, of course, the health physicists and radiation control personnel themselves. To this entire audience, what we think and, as a result of that thinking, what we do or are likely to do is of very vital importance. Consequently, we should keep in mind as we make our presentations that we are or should be speaking to an audience far larger and far more diverse than that before us in this room.

It should also be kept in mind that within the scientific, medical, and epidemiological section of this audience, there is a bitter controversy over the nature of the radiation dose-response curves for low levels of radiation exposure, a controversy that has spilled over into the public domain and serves as a root cause of some of our most serious people problems. Our data base comes largely from animal experiments. But, are animal response data applicable to the human situation? Our human data base rests on the radium dial painter cases, on Japanese casualty experience, and on massive dose therapy cases, all of these at relatively high radiation levels. So how estimate the biological effects at very low levels? Some of the animal experiments indicate that below a certain level, the so-called threshold, there are no such effects observable. This would mean that if the individual radiation results are few enough and infrequent enough, the biological system being irradiated can heal any damage as fast as it occurs. But the evidence is not conclusive, and it is for animals, not for the human system. The conservative approach, therefore, has been to assume that the biological effects are directly proportional to exposure, right down to zero exposure. No more incontestable proof for this than for the existence of a threshold, but this linear hypothesis could be right and, if wrong, would err on the side of overestimating the radiation damage done by a given radiation dose. On the basis that "it's better to be safe than to be sorry," we have adopted the more conservative linear hypothesis approach for our regulative control purposes. Now certain new epidemiological studies--still under active challenge--are interpreted as indicating that as the dose level decreases --that is, the number of "hits" is less but the energy of each remains constant--the biological effect per "hit" increases. For the life of me, I cannot dream up any mechanism that would lead to such a result. Reduced effectiveness at very high dose rates, yes, for there you could well be in effect hitting and thus "killing" the same cell several times. Since the first kill does the job, the succeeding "hits" are simply wasted and, in terms of total dose, the observed effect appears reduced. But at the low dose end, I can see no way in which the fewer the radiation absorptions, the greater their effects could come about. It is a clear-cut controversy, however, for those who believe that their results establish the existence of such a relationship believe so intensely. And so controversy reigns. Unfortunately, it is carried on at present only partially on the scientific level. It has surged over into the political domain, and subjective factors have been injected into the situation that have no business affecting the scientific analysis and scientific debate as to the corrlect radiation dose-effect relationship. This matter cannot be ignored here in this conference. I would hope, however, that its treatment here could at least edge the debate back to an honest scientific basis and eliminate the political arguments that make a reasoned and factual resolution of the controversy essentially impossible.

With that important interpolation out of the way, let us get back to the third audience that this conference should reach. That, in my estimation, is the lay, at large, public. It is fairly clear that you are already beginning to get media coverage. I hope that this is just an early sample because I would really hope that the proceedings would receive intensive coverage. Things are going to be said here that are vitally important to that public. But in order to reach the public audience, one has to know what the public mood is. And that mood at the present time is not an easy one to meet.

There are some advantages to age. When I was a child, any family that would admit that a member of that family had died of cancer would be pretty close to being ostracized. If there was cancer in the family, you covered it up. You simply would not admit it. It was just unthinkable. It was in the same category as insanity and leprosy. It was a dread disease; it still is. You could accept death from heart failure or pneumonia, you fell off the roof, or you got kicked by a horse and died. Well, those were straightforward ways of dying, unfortunate, true, but understandable. But cancer? That was different. The elements of that attitude are still with us and constitute a strong undercurrent in establishing the way in which the public will respond to any situation in which radiation is a factor. In the past 20 years, the public's public reaction to cancer has changed very considerably. People are now willing to admit to having cancer. But this is largely a surface change. Deep down the cultural fear of cancer remains, and cultural changes take a long, long time to take place. Only when effective cures for the whole panoply of cancers have been developed will the basic dread vanish.

The second factor in the public mood is the atomic bomb. I am not talking now about reactor accidents and the like. I am talking about the fact that, based on their understanding of nuclear weapons and their reaction to that understanding, large numbers of the population believe that radiation from nuclear phenomena are quite different, much more horrible, and very much more dangerous than just normal radiation like x rays, cosmic rays, and other natural radiations. Anything natural, such as potassium-40 in foodstuffs or in themselves, is obviously all right. But, anything unnatural, like "nuclear" things, devices, or operations--sort of crawls. I have difficulty believing this, but my students almost unanimously agree that they get this response time after time when they make some comment about radiation, "Oh, but that isn't nuclear radiation!" We have problems, and they are not all scientific.

The next factor that I think most of you have had to face at one time or another is the public's complete lack of confidence in the credibility of any establishment. The scientific establishment would lie without question if it felt it advisable to do so for reasons it itself ruled valid. The government establishment, as everybody knows, is completely unreliable. The medical establishment would do anything to make money. The oil company establishment obviously is raping the public right and left. Even the religious establishments are not above suspicion in some circles. You name it--any establishment is suspect. It is clear that anything an establishment says is self-serving and to be mistrusted. The result is that whenever we begin taking organized stands, a flag goes up immediately in many people's consciousnesses. If there is an establishment statement, it was the product of some high-level board of directors. If you want to get at the truth, you better corner a little guy in the organization who is willing to talk. Institutional efforts at public education have to be handled with exquisite care, for they are inherently suspect. This is one of our major problems that we have to face whenever we are dealing with the public.

Another difficult-to-deal-with facet of the public mood is one that has cropped up as a serious matter in the last decade or so. That is the apparent love-hate attitude of a significant and, in part, highly vocal segment of the public. This attitude takes it as axiomatic that all of the society's ills are due to technology. We want to keep the benefits, of course, but somehow we should be able to do that satisfactorily and still get rid of that menacing technology. The principal technology that we would like to get rid of first, and that right away, is nuclear technology. That is the one that is outstandingly evil; the one it is easiest to dramatize and condemn. It is this matter of distrust of the establishment once again. What the public does not realize is that as populations and, in particular as population densities increase, societal problems inevitably increase. So far the only way in which mankind has been able to cope with this increase is by increases in technology. That the improved technology in its turn then supports still further increases in population density and the concomitant societal problems in a so far endless spiral is obvious. Unfortunately, the public, being itself the subject population, sees clearly the connection between the growth of technology and the increase in its societal problems. It fails to see that the primary cause of its difficulties lies in itself, due to its own unrestrained growth, for which technology is only an enabling, not a causative factor. This failure in perspective leads directly to the public's current anti-technology malaise and to one of our principal public adjustment problems.

With the stage set, with a light plot in hand, and with the audiences and their moods thus defined, it is time for the conference action as specified by the program committee's script to get under way.

I have great respect both for the Conference of Radiation Control Program Directors, Inc., and for their annual conferences. I consider it a major honor to be asked to speak, particularly to be asked to keynote this convention. In addition, I was so intrigued by the proposed subject that I said yes almost without hesitation. I have been wondering why ever since. I have spent much of the last 2 weeks trying to figure out what to say. As I have told some of you, I have made a whole sheaf of notes to which I am sure you are well aware I am obviously paying little attention. I put down the ultimate note at the end of the outline 5 minutes before I came downstairs for this session. I started writing at 9:00 a.m., and I had already accumulated a good start on the outline in the preceding days. You should, therefore, be properly warned of the nature of your upcoming listening ordeal.

The title assigned to my presentation by the Program Committee is both to the point in terms of the present situation and insightful with respect to the problems it implies. It just left out one quite important thing, and that is that neither "should" nor "can" are fully meaningful in the present context. There should have been a third, and that is, "How low will we go?" So I am adding this third, ultimately definitive question. The title thus becomes, "How low should we go? How low can we go? How low will we go?"

Even if the present controversy should make it advisable to use a radiation dose-response relationship in which dose effectiveness increases with diminishing dose, I believe that the scientific, the medical, and the industrial communities can and will, ignoring dollar economics, come up with operating standards which will minimize the health hazards imposed and maximize the usefulness of radiation and radioactive isotopes. I shudder to think about the possibility of our shutting off or even curtailing seriously our use of radiation or of radioactive isotopes. Fermi always maintained that while nuclear energy is a very nice and very useful resource which we badly need, it is just a byproduct as it were compared to the contribution which the use of radioactive isotopes will make to the welfare of humankind. More and more, despite the energy crisis and the unique role that nuclear energy may, if permitted, play in its amelioration, I am convinced that Fermi is right. There is no question in my mind that the entire world will be needing nuclear energy and needing it desperately along with every other form of energy we can lay hands on. But only through the use of radioactive isotopes can we get one inanimate system to converse intelligently with another inanimate system, thus assuring coherent inter-system operation without the interjection of the sometimes fallible human linkage. That is real systems control. When one ties these capabilities to those of our ever-advancing computer technology, the possibilities for usefulness to humankind are enormous. It seems to me that we must consider very carefully before we start arbitarily eliminating or even seriously cutting back on our use of radiation and radioactive materials purely on the basis of what the public subjectively fears rather than continuing to operate on the objective basis of what science knows and can rationally conjecture.

Let us get back to, "How low should we go?" There is a real radiation hazard to human life. Concentrate enough radiation on an individual and a life will be lost. While some optimizations can undoubtedly be made, eventually the decision on what a permissible level of radiation to an individual should be depends on the value of a human life. That evaluation need not be in dollars but it has to be in terms of the worth of that life to the society of which it is a part. At that instant, the matter of "should" ceases to be one of science and technology, it becomes one of ethics. As an ethical problem, there will inevitably be as many different answers as there are ethical points of view within the society. I suspect that in reality that gets to be almost as many views as there are individuals to hold them. And every one of those answers will be a perfectly valid answer for the individual who arrives at it.

Now we may arrive at what we believe to be a scientifically justifiable "should" value and adopt it as a regulatory standard. The concerned citizen may or may not agree with our judgment. At the present time, if this citizen disagrees, he or she immediately gathers friends of like ethical conviction, they prepare signs, stage a parage, and commit acts of civil disobedience to gain media attention and thus, hopefully, marshall public opinion in support of their cause. In many cases, this tactic is at least partially effective in influencing the decisionmaking process, and we have to recognize it as a partial success.

If our citizen dislikes public displays and has not intention of paying the penalties that may accure to civil disobedience, he quietly raises a fund, hires a skillful lawyer, they challenge the standard in court on a whole array of charges and get an injunction holding the standard in abeyance pending the outcome of the trial. If the lawyer chosen is experienced and truly skillful, the trial can be delayed and delayed and delayed. When finally held, if the court ruling is adverse, it can be appealed and appealed and appealed. Recognizing that this will be the case, the pressure is on to compromise the scientifically-based standard in order to satisfy ethical judgments.

And there are other ways by which action groups are able to exercise very real pressures on the societal decisionmaking function, pressures that are out of all proportion to their numbers on their actual judgmental capabilities. They hold the whole of society hostage to the satisfaction of their own parochial ethical principles. That this situation may be both unfortunate and basically wrong is beside the point. It exists, and we must face it. Scientific fact in the area of regulatory action inevitably has to bend, at least, to ethical pressures if it is to be effective. On such an ethical basis, I certainly cannot tell you "how low we should go," because what it "should be" for me need not be what you believe it "should be" for any of you. Nor does "as low as reasonably possible" resulve the problem, for how are you to define "reasonable." That may sound simple; it means minimum damage to society's health--and I say society's health, not necessarily each and every individual's health--and maximum yield to society's welfare. And there you come again to a full stop, for again "minimum damage" and "maximum benefit" are fully as much subjective as they are objectively determinable values. Again, it is very much "to each his own." "How low should we go?" would not appear to be a very meaningful question to ask in the formulation of a regulatory code.

Now let us take a look at question number two, "How low can we go?" The answer to this one is simple. We can go just as far as God will permit and as we are willing to pay the price. It is just that simple. In fact we could intrude a bit on God's architectural design and reduce some of our exposure to the natural radiation background he has given us if we were willing to pay the rather high price that would be required for doing so. But excepting the God-given natural and essentially inescapable radiation background, it is within our power to eliminate radiation exposure. All that is required is legislative action to prohibit all uses of radiation or of radioactive materials of any kind and then the enforcement capability to make the legislated statute stick.

Since the largest source of manmade radiation stems from medical and dental uses, these should be the first to be eliminated. Following these comes industrial usage which should then be abolished. Next come an assortment of lesser exposure sources such as air travel, television (particularly color TV), and at the end of the line, nuclear powered generating stations. In different but still hazardous frequency ranges come such devices as ultraviolet suntan lamps and laser light sources. Prohibit the manufacture of any and all of these radiation sources, make their possession and use a felony, and then strictly enforce the law and the excess of radiation exposure above natural background can be reduced to zero.

I for one would object immediately and violently. I may need another operation one of these days, and I would prefer at least some x rays if not a computer-assisted tomographic or nuclear medical scan before they start carving. If there are to be difficulties to be faced, I would like to have them recognized and planned for before, not after, they have me laid open. But there are others I gather who would much prefer having their innards explored by flashlight as it were to being exposed to the irradiation that the other procedures would involve. And there would be problems galore for industry. For example, the integrity of all pressure systems (boilers, pipe lines, and the like) are proven out by x-ray or gamma ray exposures. While there are other test procedures, they are less effective and inevitably if the x-ray-gamma-ray tests are eliminated, the failure rate of pressure systems will go up and with it the rate of industrial-induced fatalities. And what holds for the results of eliminating x-ray and gamma-ray photography in the pressure system tests holds for innumerable other industrial activities which depend upon the use of radiation or of radioactive materials for their successful operation.

The habitual air traveler receives radiation exposure well above the levels permitted by the Nuclear Regulatory Commission. Every air traveler experiences some increase in exposure. Prohibit the manufacture and use of airplanes and that exposure source can be eliminated--if we are willing to pay the price in human mobility. Much the same holds for color TV. Here the radiation exposures are particularly bad, for the closer the viewer is to the screen, the greater the exposure, and children, much the most susceptible to radiation effects, habitually cluster close to the picture tube. Abolish TV, and this radiation hazard can be eliminated.

And so it goes. Radiation exposure above background levels can be reduced essentially to zero if we are willing to pay all of the societal as well as economic costs that would be involved. And they would be many, be diverse, and be economically expensive. However willing the no-radiation zealot might be to pay the costs and accept the radically altered lifestyle that would result, it is my impression that the society of which the zealots form but a small fraction will not. In effect, the question, "How low can we go?" is again somewhat less than meaningful as far as the regulatory process is concerned. Scientifically and technologically, we can go to zero excess radiation above background. It seems quite clear, however, that because "we can do" will have but little effect on what "we will do."

And this brings us to my third added question, "how low will we go?" Here I think we can begin to get some hopefully meaningful answers. At least I think we can place some of the responsibilities for producing answers, and that should indicate the way in which the future is going to develop.

In the immediate future, I think it is clear that the well-organized activist anti-nuclear movement will exercise a great deal of influence on what happens. Ventures touted as providing alternatives to nuclear projects thus gaining activist approval may profit somewhat by activist support, but they are very likely to prosper or perish chiefly on the basis of real merit in terms of perceived societal benefit and actual economic performance. Those projects which the activists charge present intolerable radioactive hazards and of which they therefore disapprove are likely to be eliminated without regard to the actual validity of the hazard claims or the true societal merit of the projects. Using a whole battery of available administrative and legal maneuvers, the progress of a disapproved project can be subjected to delay after delay after delay. Now delays, as the activists well know, are expensive. They can become so expensive that with no end to the delaying tactics in sight, the project has to be abandoned, and the activists can achieve their objective without ever being compelled to prove their case. There is no present indication that this situation will change significantly, except perhaps for the worse, in the immediate future. And as long as this is true, the question, "How low will we go?" is totally irrelevant.

In spite of this gloomy prospect, I believe this holding of the nation itself hostage to the beliefs and consequent intents of a minute activist minority of that nation's total population will be at least relatively short term. I believe that the inevitable sweep of events will break this activist domination of the national decisionmaking process in this area of concern and do so before too far into the future. As the full impact of what the prohibition of the use of radioactive materials and shortwave radiation in processes or products would mean to our economy and thus our lifestyle becomes clear, I feel sure that the public itself will reassume its decisionmaking power and relieve the well-meaning activist guardians of its welfare of their self-assumed responsibilities in this area of the public interest.

How long will the hiatus be? I wish I could say with any real degree of confidence. I can not. It might well be but a few years; it might equally well be one or two decades. I doubt that definitive social action can be marshalled in less than 2 years: I would be surprised if it took longer than the two decades.

In the long term, I obviously believe that it will be the real public, not some self-annointed surrogate that will take the ultimate action as to the future of the nuclear options in our cultural economy. This most certainaly is as it should be. I would point out, however, that when this occurs the decision could just as well accept the activist's view of cost and benefits as it could adopt that which we know to be scientifically valid. The thing that I would point out to you, and point out emphatically, is that what that public decision will be will depend not on the facts of our situation but on the public's perception of those facts. These can be two very, very different things. This begins to make very clear what the spectrum of responsibilities is and where it lies. What the public's perception of the facts is going to be depends in no small measure upon how completely and how accurately we learn to understand what the public view of our common concern really is and upon how skillfully, how sympathetically, and upon how non-exasperatedly we do so. We must get a real feel for what the public view really is factually and emotionally and try to determine how it could conceivably have gotten to be that way. If we can effectively assume this attitude toward the task we face, we might be able to do something effective about coping with it. If not, we are in deep trouble.

We must also be sure that we really understand the nature and the depth of the public's emotional response to those facts as they perceive them to be. Public belief is determined and concomitant action is fueled not by reason but by emotion, even in the most reasonable person. We must understand that only to the extent that we can reach the public's emotional base can we hope to have reason prevail in the public's actions. This is anything but easy. It does constitute, however, a very major challenge to our civic performance because the degree to which we succeed in getting the public to base its policy on fact in this area of concern instead of fantasy and unjustified fear may well determine the course of human cultural development for a long time into the future.

It seems to me that we are going to have to undertake a program of trying to understand the public. It is perfectly clear that we cannot educate the public. Trying to get the public to understand science and technology in the sense that we use the word "understand" is like trying to fill in the ocean by shoveling in sand from the shore. It should not be attempted. The public should not have to have the professional command of the scientific and technical knowledge pertaining to a given societal situation that we define as understanding in order to arrive at a valid decision with respect to a proper course of action with respect to that situation. What is required is that the public perception of the scientific and technical facts be fully compatible with those facts. This I think can be accomplished if we are willing to put in the thought and effort that will be required.

Giving lectures and writing pamphlets when effectively done are useful elements in such an educational campaign. They accomplish a lot but not nearly enough. The audience reached is much too limited to be effective in terms of actively influencing public impact on public policy decisionmaking. To reach the required public audience, we must have the support of the mass media. Now mass media communication services can be purchased to the extent funds are available, but mass media support in the sense I mean has to be earned. We must learn how to work with the media, discover their individual educational strengths and weaknesses, and their operational requirements, and find out how we, in the areas of our competence, can best support them in their fulfillment of their missions. We must never forget even in our moments of frustration and cynicism that although the mass media are indeed money-making enterprises, there is a deep-seated dedication amongst the members of the fourth estate to telling the truth and the whole truth to the best of their ability and their perception of the facts. When public report differs from our remembrance of interview, the fault may lie fully as much with our failure to explain and convince as with the reporter's bias and inability to understand.

Lesson one in gaining mass media support is that the media will not consciously be used. The instant you indicate that the media are delinquent in serving some need that you feel important, you are likely to find yourself in trouble as far as gaining support is concerned. Had the same need been presented as an aside as one of those subjects that, although vitally important, were clearly too complex and controversial for mass media treatment, the challenge would have been recognized, the matter stored for consideration, and eventually reappear as a media-initiated project, one that would welcome your help and with which you can work effectively. An effective working relationship with any element of the mass media community requires that you earn its respect, its confidence, and its conviction that you are sincerely interested in its concerns as well as your own. At the same time, it is imperative that you make clear that they must gain your respect and confidence too. The naive lamb can walk into slaughter so simply when it confronts a skilled reporter that it makes your hair stand on end. Yet it is these very techniques that we need to understand and use if we are to press our case with the public.

I would recommend an evening course in journalism to every one of you, because there are some very basic journalistic principles that we should know and follow. As scientists and engineers we bridle at headlines and lead paragraphs, but one of those basic mass media principles is this: "If you don't attract their attention and then capture their interest, they won't read your piece or listen to your report." We should take heed. A university lecture or an engineering report can bore people so fast that you have lost your audience before the first paragraph is in. Attract their attention, capture their interest, and then tell your story in a well-paced presentation, trying it wherever possible to common experience and expressing it in terms the public can comprehend.

Now different uses, different requirements, different limitations. For example, except for the documentary of an hour or more in length--in whose production I would guess very few of us are likely to get involved--TV is primarily useful where short, clean cut, almost "yes-no" statements of fact can be put together for presentation. When these can be included as items in a news or magazine format, they can carry tremendous impact. But it must be remembered that like a black and white lantern slide, they have strict limitations. A lantern slide is only good if the focus is sharp and the contrast between black and white is intense. It is only fully effective if it confines its informational content to a single subject and one at that whose message is simple enough for it to be depicted in a stark, uncluttered format. A "busy" slide that tries to tell too much defeats its purpose. These same limitations apply to a TV new spot or interview. They are no medium for attempting to explain a complicated or abstruse subject or to debate the ins and outs, the rights and wrongs of involved situations.

Every serious photographer knows that the properties of the slow photographic emulsion that make it ideal for presenting an informational message also render it essentially useless for recording the full range of information that is required in a truly valid photographic representation of any physical scene. Its "gray scale" is too short. That is, the properties of the emulsion are such that can only differentiate between different shades of gray in such crude fashion that the photographic reproduction it produces is essentially fully opaque or fully transparent. An emulsion with a long gray scale permits registration of the subtle differences in light and dark that makes faithful photographic reproduction possible.

The mass media analog to the photographic emulsion gray scale limitations lies in the media time scale or line restrictions, the amount of information that can be effectively presented within the standard TV or radio program intervals or in the number of lines of print that an editor is willing to devote to a single informational packet. As pointed out above, for TV the spots that are usually achievable are usually very short and the quantity of information that can be effectively transferred to the viewer therefore small. The impact, however, partially for that reason, can be great.

In general, the time limitations on radio are not as severe as they are on TV. There are short spots that can be very valuable. Many individuals, businesses, and other institutions turn on their radios to a favorite station and leave it on all day while they, their customers, their clients, and their employees go about their affairs as usual. Spots on such station programs are heard and listened to by hosts of people who would never think of turning on an "educational program." And these spot messages if well done are not only listened to but they register and are remembered by an enormously large and diverse audience.

Fifteen-minute periods--minus an "announcement" or "message" or two--can be wangled on radio and even upon occasion on the Public Broadcasting Service radio and TV programs. With careful planning, editing, and rehearsal periods this long are adequate for "explanations" of simple scientific and technical phenomena and for the analysis of simple but important system operations. If you are effective at it, have the stamina and guts to stick it out, and usually if you are willing to donate your effort, you can upon occasion work yourself into a weekly "science and technology" column. Here by discourse and interview

n really do a public education job--hopefully on a much broader base
we go."

re faced with explaining a complex phenomenon or with analyzing a
eration, neither TV or radio can do the job as well as print. If you are
r informational trap with some attention-arresting statement about
hat will invite at least, and, hopefully, really compel reportorial
it, cooperate fully, but with obvious professional candor. That is, be
rawbacks and difficulties as in presenting breakthroughs and benefits.
stice be cynical, and you must handle your end of the interchange in
reporter becomes convinced that the accurate dissemination of the
im is indeed your basic concern, not some free personal advertising.
more personal relationships of this kind where the reporter feels free
for verification and clarification of some wild science or technology
n on the press wire, you have it made. With suitable care, you now
available for your explanations of the complex situations that the TV
ion modes cannot handle. True you have to hold your breath at what
ay do to you, and you must learn to write an intriguing lead paragraph
ly and literately done, you can usually get enough lineage to present
ical, and comprehendible presentation of your subject. It takes time,
f skills other than those of scientific and technological competence.
great, the stakes in terms of the common weal are high, and the
of having produced a public education lesson, be it a TV spot or a
be seen, heard, or read by thousands and that will certainly resolve
are deeply rewarding.

kinds of public education lessons that we must learn. And, if these
e fulfilled, we of the scientific and technological community are the
hem. There is no one else, however, willing, that is capable of doing
uld hope, learn to answer the public's scientific and technological
nt clarity and precision to assure that the policy decisions it makes
e actual facts of the situations involved and are not based on an
perception of those facts. I fear it would be much more difficult if
or any other segment of the public to master the fields of science
icient depth to accomplish the same objective. The relatively few
ters who have done it have essentially made themselves qualified
ic or engineering communities. They are the exceptions and, impor-
ons are, the task is so immense and so important that their output
educational responsibilities resting on each of the rest of us.

this matter of the "public understanding of science and technology"
nt. We function right at the interface between the public and the
ical operations which serve that public and upon which that public is
ere there is an adequate understanding of science and technology on
we serve, there is usually very little difficulty in building a strong
of well-balanced regulations. Where the public view is based on
ed, or often even false, perceptions of the actual scientific and tech-
oblems in devising and implementing reasonable regulations can be
If we want our responsibilities to be effectively discharged, it
educational phase of our operations some very careful and hopefully
me dedicated implementing attention.

essage I would bring to you as you begin this conference. Your
I hope that its influence does indeed sweep out directly or indirectly
s that so sorely need to be aware of its content.

REPORT on CURRENT and PROJECTED FEDERAL RADIATION PROTECTION ACTIVITIES

William A. Mills
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DR. MILLS: My comments will be brief and separated in two parts. The first part addresses the subject of this portion of the program: "Current and Projected Federal Radiation Protection Activities." The second part, however, will be a departure in that I want to express some personal views.

The theme of the Conference is "Radiation: Minimizing Exposure; Optimizing Use." Since EPA is not a user agency, obviously we emphasize the former objective exclusively. This is not to say that we do not optimize, but that optimization is performed only in the context of maximizing the reduction of health risks per dollars spent. In this way we attempt to give the public its biggest protection bang for a buck. Frankly, I do not fully understand the involvement of professionals in radiation protection in the use of radiation.

In keeping with at least one part of the theme, EPA has continued to emphasize implementation of its legislative and other mandates concerning environmental standards for air emissions, radioactive waste, and the various other activities associated with ionizing and nonionizing radiation. We have proposed general and RCRA criteria for waste, drafted recommendations to the State of Florida on radon daughter exposures, and are finalizing our recommendations on Federal guides for handling transuranics in the environment. Each of these actions is directed toward minimizing exposure and has some unique features that may find use in other areas of environmental concern. An example is the UFC standard of 25 mrem/yr for normal operations of the uranium fuel cycle. Although the selection of the value represented our judgment of what is "as low as reasonably achievable," the magnitude of the value is about the variation in natural background radiation dose for most of us and this might serve as a guidepost for judging acceptabilities of pollutant levels. Another example is a risk of less than 1 in 10^6 per year as the basis for the transuranic guide, and its possible application to many correctable situations involving environmental contamination, not just radioactivity.

We have not been overlooked in terms of resources allocated to our efforts. The budget to perform our tasks has grown appreciably in the last few years. Unfortunately, our staff positions have not increased proportionally, and therefore, more of our effort is directed to contract activities than we would like.

Some contracts do have exceptional public benefit, and I am pleased that in May 1976, before the tide of controversy over the effects of low dose, we saw a need for an updating of the 1972 BEIR report. That updating is now successfully completed and the National Academy of Sciences presented its report to us last week. I will not try to give details of the BEIR III report, but it certainly cannot go without notice that ORP's risk analyses based on the 1972 BEIR report and used by many others, have not been extreme in either overestimating risk or underestimating it, and numerically appear consistent with findings of BEIR III.

Our published 1975 policy, which stated in essence that we would use a linear nonthreshold dose-effect relationship in estimating risk and that the actual health impact at expected environmental levels is not observable, remains valid. I am proud that we have taken such an official stand and that we were willing to openly provide risk estimates for evaluating our decisions. As you know, officially stating risk estimates may be "dangerous to your health." This now leads me to the second part of my comments, which are likely to be "dangerous to my health."

Our most serious challenge today in radiation protection is not which radiation source to address by minimizing exposure or optimizing its use. It is simply the problem of lack of public confidence. Although we Feds are the most obvious targets, I submit that all of us in radiation protection, regardless of where we participate, are to some extent targets.

Certainly, we have let controversy over the low-level effects of ionizing radiation become such a dominating factor, particularly in the media and in our own organizations, that I am not sure where any of us stand. As such we have lost sight of a traditional emphasis that "radiation needs to be respected but not feared" and to some extent have allowed fear to drive policy and even operations.

-- We must not be in fear of receiving a needed medical x-ray; we must respect, however, the exposure to minimize it.

-- We must not fear the releases from nuclear power generating stations, but we must respect the potential exposures and be ever cautious to minimize them by whatever means required.

-- We must not fear a move from one geographical location to another because of differences in natural background radiation, but certainly we must respect the exposures that might arise from human disturbance of the natural state.

It seems to me that what has happened is that we have allowed many decision-makers to weigh inconclusive studies more heavily than the wealth of knowledge accumulated from the expenditure of almost $2 billion in radiation research.

The actions proposed are directed toward more studies to prove what our best scientific evidence tells us is undemonstrable and for more changes in institutional responsibilities. The latter in some cases may not be based on providing increased public health protection but rather on "turf protection" and even distrust among agencies. Obviously, political judgments are important but the bottom line in radiation protection is being able and willing to tell the concerned public what the risks are and how they are being protected--responsibilities which I believe involve scientific and technical judgments. Certainly al judgments made on behalf of the public by those who serve the public must reflect common sense and the best intentions.

All of us in radiation protection must provide adequate radiation protection but we must also protect the taxpayer's investment in us. I have no desire to provide extreme unwarranted protection against radiation risk and in doing so pass on to my offspring and future generations a legacy of foolish spending and an unnecessary debt.

I have no quick remedies to suggest, but I do believe that Federal and State leaders in radiation protection can begin the process by at least publicizing those things we do agree on and even those things on which we are in disagreement. Perhaps we can begin by looking at BEIR III as a possible basis for agreement on what risk estimates to use in making decisions. It may be necessary that we state that a level of dose is safe, fully recognizing that such a statement is not void of any risk to the recipient in the absolute sense. Otherwise, any risk is being taken as to mean that any dose is unsafe even in the practical sense. For better public understanding the practical definition of safe may have to be our guidepost rather than the absolute definition. Such an agreement could also be useful in deciding which epidemiologic studies are warranted by Federal and State investigators.

Since State leaders are probably in a better position to influence public views than the Federal sector, because of proximity and public confidence, I believe the Conference could be highly effective in getting the straight story publicized on the effects of ionizing radiation. I encourage you to do so.

These suggested ideas are obviously technically oriented. I have no suggested quick solutions for turf fights and mistrust--my only thought is that we keep the public's interest up front and in time perhaps it will resolve itself and some restoration of public confidence will be attained. It will not be an easy task--we will appear to many to be wearing black hats. That hazard we must accept.

I must note that the Feds have black on their name tags--perhaps the Conference has great foresight.

MR. RYAN: I want you to know that I dutifully prepared a 27-page briefing on all of the various activities we have performed over the years and I am dispensing them now.

The topic we have been assigned is, "Current and Projected Federal Radiation Activities by NRC," and I think I can answer that in one word, "investigation." Investigations will be the current and projected radiation activities by NRC into the indefinite future. There will be the NRC study of Three Mile Island, there will be a Presidential Commission, there will be various Congressional inquiries, there will be a GAO report, there will be public interest groups, and there will be various other organizations, public and private, looking at it.

Surely, I think, in Three Mile Island, we have seen some of the most cherished illusions of a generation fly out of the window overnight. David Jaeffey, who is a former NRC project manager, now consultant in the nuclear energy business, said: "What really spooked us at Three Mile Island is that we had a loss of coolant accident, the most severe kind, from a sequence of events which should never have happened. It has made us reassess our whole approach to analyzing accidents."

"Reassessment" here is the keyword and I think it will be the keyword into the indefinite future. NRC will be reaassessing its safety requirements; States will be reassessing emergency procedures. And we all have some tough judgments to make; particularly in the political arena, in Congress, in the next 2 years, about nuclear waste, transportation, low-level exposures--about a host of things. I cannot bring you any answers about Three Mile Island because the investigations, as I say, are just beginning. As we are talking here this afternoon, there is a meeting going on in Washington on the Ellipse; my estimates of 20,000, 30,000, perhaps 40,000 people who are very concerned about nuclear power and its implications to public health and to the environment.

We can say, without any hesitation at all or without any doubt for that matter, that it is and will continue to be a supercharged, emotional issue. There are very few people who are indifferent to it. The public debate has been joined, and where it will lead us at this point, we cannot tell. What can we do in this debate and in the reassessment which I say is going on? The answer, I put to you, is that we can tell the truth.

We need a prolonged period of truth telling about radiation. We must take care in the months ahead to speak the truth about radiation and to be careful neither to exaggerate its risks nor to underestimate them. We should keep uppermost in our minds, while doing this, our obligations as public servants or our obligations particularly to protect the public health and safety in every aspect of our work.

I thank you for your kind attention, I want to express the hope that this Conference will be as successful this year as it was last and that the year ahead will be filled with success. I am very proud that NRC is associated with the Conference and is allowed to support it; it is most important work and you have most dedicated members. Remember that we work in the public interest.

MR. BENSON: I appreciate the opportunity to join you here today in John Villforth's absence, who, as you may know, is continuing to labor over the Three Mile Island situation. He has asked that I extend his regrets and best wishes for a productive conference.

It has been an extraordinary year, with the promise of increased public and Congressional interest and investigations into the generic issues related to medical x-ray exposure, exposure of civilian and military personnel during the 1950's and 1960's atmospheric nuclear weapons tests, and occupational exposure of nuclear power plant and naval shipyard workers. And ultimately, the question of compensation for those who may have incurred adverse health effects from exposure to radiation will be addressed.

Let me begin the presentation by sharing with you some good news and some bad news. The bad news, which was just recently announced, is the resignation of the Commissioner of the Food and Drug Administration, Dr. Donald Kennedy (effective June 30). As you may have learned from the news media, Dr. Kennedy has accepted a post at Stanford University, the institution from which he originally came. His departure represents a significant loss to BRH because of his vigorous leadership and support regarding radiological health activities. The positive side of this decision is the legacy he will leave behind that will help to foster the continuation of the vision and operational strengths he brought to the FDA during his tenure. The impact in Washington to the announcement was perhaps best articulated by Senator Kennedy, who said he was "saddened that a first-rate Commissioner was leaving FDA." No successor has yet been named--however, in light of increased public demand for more intensive Congressional scrutiny of Federal radiation programs, in addition to the medical x-ray directive made by Secretary Califano during his February 27 press conference, I would expect that no diminution of FDA's role in radiation protection will occur.

I have already mentioned--and I think it comes as no shock to anyone here--that a significant rise in public concern over the health effects of radiation has taken place over the last 17 months or so. Senator Domenici (of New Mexico) may have characterized this trend best when he addressed the Second Congressional Seminar on Low-Level Ionizing Radiation last year. He said, "Recent reports...have made it clear that the controversy surrounding the question of possible hazards to human health from low-level radiation has not only not diminished in intensity, but is increasingly becoming the subject of widespread attention." Another indicator of this spiraling interest on the part of the private sector is the plethora of news accounts which have made front page headlines. This year, (i.e., subsequent to the Rogers' Hearings), more than any period in the history of radiation protection, we have accumulated an impressive volume of material--over 300 newspaper and magazine articles.

This ground swell of public concern precipitated major investigative and legislative action by the Congress during the past year. In the 95th Congress alone, as many as six committees and subcommittees, either through hearings or reports, exercised their oversight powers to review the efficiency and effectiveness of Federal radiation protection activities. Already this year in the new Congress, three subcommittees have held hearings to discuss certain radiation problems. More are sure to follow.

An exhaustive series of oversight hearings (held throughout 1978) by the House Subcommittee on Health and the Environment, chaired by former Congressman Paul Rogers, sparked the Administration and other Congressional committees into reexamining the policies and organizational framework and authorities concerning radiation protection. Let me capsulize for you the events that resulted from these hearings.

One major outcome of the Rogers' Hearings was the issuance of a directive by the President to the Secretary of HEW to coordinate the establishment of a program on: (1) radiation bioeffects research; (2) public information on radiation protection; (3) care and benefits for persons potentially affected by exposure to radiation; and, (4) preventive actions to reduce unnecessary exposure. This task was undertaken by an Interagency Task Force on Ionizing Radiation (comprised of officials from HEW, DOD, DOE, VA, NRC, and EPA), and spearheaded by the Department's General Counsel, Mr. Peter Libassi. Tomorrow you will hear from Ms. Kathy Blackburn who actively participated in the preparation of the various work group reports, now in draft form and soon to be finalized for submission to the White House. So as to not steal Kathy's thunder, I shall confine my remarks about the "Libassi Report" to those areas that directly impinge upon BRH's radiation responsibilities.

Secretary Califano, in the Februrary press conference which announced the release of the draft workshop reports for public comment, directed FDA to accelerate and intensify its medical x-ray program. Specifically, the Secretary asked that current programs related to the development of x-ray referral criteria and guidelines for the credentialing of radiologic personnel be stepped up. Much has been done in both of these areas and I will elaborate on each in just a few minutes.

Another offshoot of the hearings was the passage of legislation (P.L. 95-622) that mandated HEW to "establish a comprehensive program of research into the biological effects of low-level ionizing radiation." The Director of the National Institutes of Health, Dr. Donald Fredrickson, was asked by the Secretary to oversee and insure that this mandate is carried out.

The development of an Interagency Radiation Research Committee is in its embryonic stages and we are pleased to have an active part in this effort. The prime goal of this initiative is to place the decisionmaking aspects of Government-sponsored research (e.g., establishment of a research agenda and priorities, dissemination of research data, determination of the proper location in the government for certain types of research, and so forth) in an agency charged with safeguarding the public health.

Another law enacted by the Congress indirectly involving the Department is P.L. 95-601. This Act directs NRC, in conjunction with EPA and consultation from HEW, to design research protocols for future epidemiological studies on the health effects of low-level ionizing radiation. Dr. Charlotte Silverman, Deputy Director of our Division of Biological Effects, has been designated as the HEW representative for this undertaking.

A final initiative stimulated by the Congress impacting on the Bureau of Radiological Health and formalized by a Presidential directive, was the reopening of past studies investigating the possible link between exposure to atomic bomb test fallout and leukemia and other forms of cancer, as well as thyroid disease. FDA's role is to conduct a new study to ascertain the feasibility of locating residents in the fallout areas and to reevaluate their health status. This issue, as you may be aware, was the focus of recent joint Senate-House hearings in Salt Lake City and Las Vegas, which will be continued throughout this summer.

Apart from all the excitement generated from Capitol Hill, we did manage to make some headway on our traditional responsibilities. I would be remiss if I did not start this part of the presentation by noting that last year marked a milestone in the history of the Radiation Control Act. In October, the Bureau commemorated the tenth anniversary of the signing into law of the Radiation Control for Health and Safety Act.

A major advancement has been made in the area of (radiation) medical devices.

BRH/BMD Agreement - After prolonged negotiations, an agreement between the Bureau of Radiological Health and the Bureau of Medical Devices has been reached. We anticipate this will have a substantial effect on the future activities of BRH. The agreement, approved on February 16 of this year, delineates the working relationships and procedures to be followed by both Bureaus in regulating radiation-emitting medical devices, and identifies BRH as the lead Bureau for some 188 (of the approximate 4,000) medical devices.

According to the terms of the agreement, BRH, as lead Bureau, will be responsible for the safety and effectiveness of both radiation-emitting electronic products as well as those not defined as "electronic products"; e.g., cobalt-60 teletherapy and brachytherapy sources, and accessories or components that influence the quantity, quality, or direction of radiation produced, such as nuclear medicine scanners, screens, and film processors. Thus, BRH will now develop programs to address potential problems dealing with electrical, thermal, and mechanical hazards, in addition to the traditional radiological problems.

Amendment to 1000.16 - Another action taken recently by the Bureau is the proposal to alter Section 1000.16 of the diagnostic x-ray standard. This amendment, which we expect to take effect on August 1 of this year, would revoke the present requirements prohibiting the assembly of (the relatively few) uncertified components into any existing (uncertified) diagnostic x-ray system, or the reassembly of uncertified components associated with a change in ownership and relocation. An in-house study on which this action is based concluded that the current regulation, if maintained, would not be cost effective. I would ask that any questions you might have on this be deferred until Bob Phillips' talk tomorrow.

State Compliance Contracts - On the issue of State contracts, 14 new contracts were awarded, bringing to 34 the number of States participating in our x-ray compliance program. The contracts all took effect in September 1978, but vary in length from 12 to 16 months, so that in the future all will not need to be renegotiated in the last quarter of the fiscal year. To date, contract States have performed over 7,800 compliance inspections; present contracts call for the conduct of 4,800 additional inspections this year. Approximately 1,800 FDA inspections (400 performed thus far) are planned for fiscal year 1979, bringing the total number to over 4,000.

Within the next few months, all the present contract States, as well as those not under contract, will receive a proposal inviting them to contract for x-ray compliance field testing.

X-Ray Non-Compliance - As you know, we have had a chronic problem with high rates of non-compliance with the diagnostic x-ray standard. Data continues to indicate an elevated and unacceptable rate. To a large degree, this situation results from inadequate and improper installation practices on the part of assemblers in the field. Consequently, we have begun to impose greater sanctions in the form of civil penalties against assemblers who are repeat offenders. This is based on the assumption that assemblers will now begin to take measures to prevent future noncompliant installations. Injunctions will be considered if additional restraint is necessary, that is if past non-compliances are not corrected.

In the use area, the Bureau has set in motion new programs that could do much to effect reductions in unnecessary medical x-ray exposure.

Referral Criteria Conference - Last fall, at the suggestion and with the help of Congressman Rogers, HEW held a National Conference on Referral Criteria for X-Ray Examinations. The purpose of the Conference was to explore means of reducing unproductive medical radiation exposure and curtailing needless health care costs.

The Conference brought together representatives of health-related Government agencies--both State and Federal, medical specialities, third-party insurers, and the legal profession. Gerry Parker, Chuck Hardin, and Jane Fisher from the Task Force on Efficacy of Applications of Radiation in the Healing Arts represented this Conference at the 3-day meeting. Workshops were convened to formulate strategies for developing, testing, and implementing the use of referral criteria for radiological procedures. The Conference proceedings, which are currently being reviewed by participating organizations are scheduled to be published shortly.

In keeping with the recommendations put forth by the Referral Conference, the Bureau is sponsoring a series of panels comprised of radiologists and referring physicians, that are charged with the task of establishing sets of referral criteria for certain radiologic examinations. Three panels have been constituted thus far; they are currently preparing criteria for x-ray pelvimetry, administrative chest x rays, and voiding cystourethrograms in children. Secretary Califano's directive has added further impetus to this venture. Bill Properzio is scheduled to talk in more detail about this tomorrow afternoon.

RT Credentialing - A second component of the Secretary's directive to FDA deals, as you may recall, with the development of "guidelines for education, certification, and testing of x-ray, nuclear medicine, and radiation therapy technicians." BRH has worked closely with the Conference's Task Force on Credentialing Radiation Allied Health Operators, which I understand has made great strides toward the production of detailed credentialing recommendations. I would hope that this type of collaboration can continue in the future as we proceed to develop national guidelines in this area. FDA announced its plan to formulate specific guidance on national standards for the qualifications of medical radiation technologists in a Notice of Intent, that was published in the FEDERAL REGISTER on March 13, 1979. Both Joe Nanus and Polly Story will speak on this subject on Thursday morning.

Quality Assurance - Quality assurance activities, both private and public, for diagnostic radiology, have grown rapidly in the last couple of years. Our specific efforts to encourage quality assurance activities in diagnostic x-ray facilities now include a focus on smaller facilities. We have initiated a study of existing quality assurance programs in smaller hospitals and clinics to try to discover the elements of a successful program for such facilities. To encourage more rapid acceptance of quality assurance, the Bureau has contracted with the American College of Radiology to hold a small conference of professionals to discuss what action should be taken to motivate the radiological profession to implement programs in their facilities. BENT and DENT are still progressing - we now count 45 States which are in some phase of the BENT program and 38 in DENT. We have set our sights on new problems and survey techniques. This includes a pilot test of CT survey procedures in preparation for a larger study that will get underway later this summer and fall. The purpose of this CT survey is to evaluate imaging performance and dose as well as to obtain a profile of how CT units are being utilized. A preview of the pilot study will be presented in one of the table clinics.

Data Collection - In the area of data collection, we have awarded contracts entitled, "Followup of Extreme NEXT Exposures - Research Causes of Extreme Patient Exposures from Diagnostic X Rays," to five States; several other States are voluntarily participating. Data are just beginning to accumulate and should give all of us some insight into the variability of patient exposures from diagnostic x-ray examinations.

In the area of ionizing radiation bioeffects, I have already discussed the "Utah-Nevada" feasibility study, which will determine if enough children involved in the initial work can be located to warrant a full-scale epidemiological followup study. Other projects in the ionizing area include two epidemiological studies involving I-131 --one is a multi-clinic study to examine bioeffects associated with its use in children for diagnosis of thyroid disease, while the second will look at its application in therapy for hyperthyroidism.

I have attempted to provide a general overview of outstanding events that have occurred over the past year. Obviously, time does not permit a complete review of all of the

Bureau's ongoing activities. You will hear in much more detail during this week about what we are doing in a number of areas and the general thrust of future programs.

I would like to spend my last few minutes to briefly mention other miscellaneous events, both within and outside FDA, that may shape the course of future Bureau endeavors.

A GAO report entitled, "More Protection From Microwave Hazards Needed" (November 1978), called upon FDA to expedite its promulgation of a microwave diathermy standard, expedite reviews of manufacturers' reports on such products, and to improve diathermy operator training.

Legislation (S. 500 - Randolph), which is pending in the Congress, would mandate HEW to set Federal standards for licensure of radiologic personnel and accreditation of schools that train them. States would adopt and implement model standards on a voluntary basis, (Hearings reportedly will be scheduled after May 15, 1979.)

A report by the Senate's Governmental Affairs Committee (Ribicoff/Glenn) recommends sweeping reform of Federal radiation health and safety programs. This report, coupled with the draft "Institutional Arrangements" report (released April 17) developed by the "Libassi Task Force," are now undergoing review and deliberation by the public and the Congress. Taken together, these reports will likely serve as the basis for possible legislative or administrative changes. Just this past week in fact, we learned that legislation will be jointly introduced by Senators Ribicoff and Glenn proposing structural modifications in Federal radiation protection programs.

A report by the staff of the Senate's Committee on Commerce, Science, and Transportation (Cannon) addresses a wide scope of radiation problems with respect to both ionizing and nonionizing radiation. Considerable emphasis is placed on: (a) the need for increased effort to reduce unnecessary medical x-ray procedures; (b) adequate training for persons who administer radiation to patients; (c) nonionizing safety standards (for products, workers, and the public); and (d) centralized coordination of Federal radiation research and regulation at the White House level.

Just prior to adjournment of the 95th Congress, Congressman Rogers, in lieu of formal legislation, inserted into the Congressional Record (on October 14) a comprehensive set of strategies and recommendations regarding medical x-ray protection. These proposals may serve as the framework for further hearings by the House Health Subcommittee.

A recent NBS/BRH dose delivery survey revealed evidence that a significant percentage of Co-60 teletherapy units did not deliver the prescribed treatment dose. These findings have triggered us to initiate remedial actions and further analyses. For example, the Bureau is preparing to conduct a similar study of medical linear accelerators which may show even greater problems. To deal with these treatment inadequacies, and in response to the Notice of Intent published in March of last year, we are also building a quality assurance program for radiation therapy. The principal mechanism for implementation, i.e., regulation versus recommendation, is still a subject of intra-Agency debate.

Also in the area of radiation therapy, we are closing in on final publication of recommendations with respect to radiation treatment for benign diseases, which have been evolved from the 1977 review by the the National Academy of Sciences.

In the microwave/RF area, we are currently participating on a committee, formed under the aegis of the Interagency Regulatory Liaison Group (IRLG), itself formed in 1977 by the Consumer Product Safety Commission, EPA, OSHA, and FDA, to address in a coordinated manner, the risk of human exposure to RF and microwave radiation.

Since its inception, the Committee has not only brought the regulatory efforts of the four agencies closer together, but has drafted a statement of work for a contract with NAS to develop a critical appraisal of RF/microwave bioeffects. Additionally, the Committee has developed a draft philosophy of radiation protection and identified RF sealers as a pressing concern for interagency action and has begun to develop a multi-lateral strategy to deal with the problems associated with their use.

A very recent development that may have a substantial effect on the Administration's overall nonionizing radiation research program is the establishment of an interagency task force on the Biological Effects of Nonionizing Electromagnetic Radiation (BENER). This task force was formed at the request of the Director of the Office of Science and Technology Policy (of the Executive Office of the President), under the auspices of the National Telecommunications and Information Administration (of the Department of Commerce). It has been asked to prepare "a detailed plan for a Federal program on understanding the biological effects of nonionizing electromagnetic radiation." The upshot of this action will be the development of a "comprehensive, coherent program recommendations for Federal (including BRH) activities to be included in the President's FY 1981 budget.

Switching to the light area, the Bureau is currently in the process of readying several documents for FEDERAL REGISTER publication. The sunlamp standard, in final full form, is due to be published in the next few months, as is the proposed regulation for mercury vapor lamps.

A Notice of Intent for PUVA (Psoralen Ultraviolet-A) therapy should also appear in the FEDERAL REGISTER soon. The NOI is targeted at equipment recommendations, an initiative endorsed by the American Academy of Dermatologists, which itself is developing guidance for the training of clinicians and technologists who provide PUVA therapy to patients.

Because of greater audience appeal for different types of laser light shows, the use of lasers as an entertainment medium is rising at a rampant rate. Later this week you will hear a panel discussion covering this subject in more detail, and for that reason, I will simply say that we believe that the situation is under adequate control.

Additionally, let me note that we are committed to helping equip you with the necessary information to deal with compliance matters involving laser light shows. On April 23-24, for example, we cosponsored with the State of Wisconsin a training course designed to provide basic concepts associated with hazard evaluation; the reported reaction to this program was very favorable. So we hope to build partnerships like this with many more States, in an effort to facilitate more effective control over the safe use of these products.

Research is also continuing to explore the still uncertain health implications of exposure to a variety of light sources. A contract to provide detailed spectral measurements could well serve as the vanguard for knowledge about noncoherent light source emissions. Work on potential human photosensitivity, and the need to test for phototoxicity in the evaluation of drugs, food additives, and cosmetics is also underway.

Over the past year, greater public and media attention has been paid to the use of ultrasound, both as a treatment and imaging modality. This heightened interest was evident during hearings last year before the Senate Health Subcommittee at which FDA Commissioner Kennedy testified on the potential risk of exposure to diagnostic ultrasound in obstetrics, and cautioned against its indiscriminate use.

Shortly after the hearings, FDA published a NOI for diagnostic ultrasound equipment announcing possible future actions such as recommended use procedures, training criteria for users, regulations or recommendations for equipment performance, and informational requirements. It elicited public input on a number of questions and conceptual criteria. Bob Britain will talk more about this on Tuesday.

In addition to the NOI, we have supported the development of a phantom that can be used for demonstration purposes, participated in ultrasound quality assurance workshops, and are developing a quality assurance manual for possible adoption by the American

Institute of Ultrasound in Medicine (AIUM). And, on February 17 of this year, our performance standard for ultrasound therapy took effect.

Insofar as ultrasound research is concerned, the Bureau is continuing its bioeffects program, which has reported some preliminary data that will be presented at the World Federation of Ultrasound meeting soon.

Just a quick word about training. A Training Coordination Section has been established in our Division of Training and Medical Applications for the purpose of according greater attention to the National Radiation Control Network (NRCN). Our enhanced capacity to expeditiously produce and disseminate video presentations on critical issues was recently demonstrated by the distribution of a condensed version of the April 4 Senate Hearing on the Three-Mile Island accident. This reorganization we believe, will contribute greatly toward the fashioning and upgrading of systems to route these tapes to you more rapidly. (To date, we have nearly 400 videotapes in our inventory.)

As I said at the beginning of my talk, it has been an extremely eventful year. The prospects of an expanded role for the Congress toward resolution of the well celebrated problems concerning radition and its impact on public health loom large. It seems likely that that definition of Federal radiation protection authorities and jurisdictional issues, the assessment of the adequacy and openness of radiation research, and the adjudication of the radiation compensation dilemma will increasingly fall within the purview of the legislative branch of the Government.

I am also convinced that, in view of the proliferation of public concern and uncertainty over questions centered around the health consequences of exposure to radiation, that the regulatory onus which we share, in terms of establishing and justifying radiation safety standards will become even greater. And certainly, the whole question of risk assessment will take on greater importance, especially now with the newly released BEIR III report.

It is difficult, without a crystal ball, to give you a precise prognosis for the future of radiation protection, but I do think that answers to nearly all of today's societal questions depend upon the furtherance of public understanding of the complexities of problems that confront us daily. To that end, the Conference's role is clearly of critical importance. We will certainly continue to do our part.

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GENERAL SESSION: LOW LEVEL RADIATION

Moderator: *Thomas M. Gerusky*, Pennsylvania

PERSPECTIVE FROM BEIR REPORT, 1979
Albert W. Hilberg, National Academy of Sciences

ALARA -- RADIATION RISKS AND THE NEED TO KEEP EXPOSURES "AS LOW AS REASONABLY ACHIEVABLE
Allen Brodsky, Office of Standards Development, U.S. Nuclear Regulatory Commission

FINDINGS AND RECOMMENDATIONS OF THE INTERAGENCY TASK FORCE ON RADIATION EXPOSURE
Kathleen Blackburn, Assistant Chief Counsel for Enforcement, Office of Legal Counsel, FDA

DEVELOPMENT OF RADIATION PROTECTION GUIDANCE FOR OCCUPATIONAL EXPOSURES
Luis F. Garcia, Project Leader for Occupational Radiation Protection Guidance, Office of Radiation Programs, U.S. Environmental Protection Agency

NRDC's POSITION ON LOW-LEVEL RADIATION EXPOSURE
Arthur Tamplin, National Resources Defense Council

GENERAL SESSION: MEDICAL RADIATION ISSUES

SESSION: Regulations - Pain or Panacea

Moderator: *Alice Dolezal*, Minnesota

REGULATIONS IMPACT ON RADIOLOGY
Otha W. Linton, Director of Government Relations, American College of Radiology

RADIATION CONTROL REGULATIONS ARE NECESSARY AND EFFECTIVE
Marshall W. Parrott and Darrell L. Hocken, Radiation Control Section, Oregon Department of Human Resources

PLANNING REGULATIONS CAN COMPLICATE YOUR LIFE
Jerome H. Shaprio, Director of Radiology, City of Boston Department of Health and Hospitals

THE IMPACT OF REGULATIONS ON THE HOSPITAL PHYSICIST
William R. Hendee, Department of Radiology, University of Colorado Medical Center

COST/BENEFIT OF THE DIAGNOSTIC X-RAY STANDARD--A SECOND LOOK
R. Phillips, H. Rudolph, and T. Shope, Bureau of Radiological Health, FDA

SESSION: REFERRAL CRITERIA FOR MEDICAL RADIATION PROCEDURES

Moderator: *Jerome H. Shapiro*, Massachusetts

WHAT SHOULD/SHOULDN'T THE RADIOLOGIST BE ASKED TO DO?
William E. Jobe, Department of Imaging, Swedish Medical Center, Denver, Colorado

WHY THE PHYSICIAN NEEDS AN X-RAY
Mark Johnson, University of Oklahoma School of Medicine

REFERRAL CRITERIA--THE UNMET NEED TO OPTIMIZE RADIATION USE
Mark Barnett, James L. Morrison, and William S. Properzio, Bureau of Radiological Health, FDA

THIRD-PARTY ROLE IN REFERRAL CRITERIA
W. Fred Lucas, National Heritage Insurance Company

STATE ROLE IN BETTER UTILIZATION OF X-RAY TECHNOLOGY
Jane R. Fisher, Bureau of Radiation Protection, Pennsylvania Department of Environmental Resources

BEST DOCUMENT AVAILABLE

[illegible] PERSPECTIVE FROM BEIR REPORT, 1979

Albert W. Hilberg, M.D.
National Academy of Sciences

[illegible] y Robertson J. Augustine, Ph.D., Director of Operations, Office of [illegible] s, Environmental Protection Agency)

[illegible] xamination of several proposals that have been made as a basis for [illegible] n human populations of low levels of ionizing radiation, a committee [illegible] ch Council has selected one that extrapolates a straight line from [illegible] ure data down to background levels and assumes that there is no [illegible] diation ceases to have adverse effects on humans.

[illegible] linear non-threshold hypothesis and the BEIR Committee in 1979 [illegible] sition that the linear non-threshold hypothesis is a reasonable way [illegible]

[illegible], the committee's estimate of possible risk from ionizing radiation [illegible] 53 excess cases of fatal cancer per million persons exposed per rad [illegible] ure, and 68 to 293 per million persons exposed per rad per year for [illegible] posure.

[illegible] of radiation any single individual receives can vary considerably [illegible] pe of residence and occupation, the national average approximates [illegible] year, almost all of the radiation coming from natural sources and [illegible]. Workers in certain occupations may, however, receive almost a [illegible] year. In addition, some individuals may be more vulnerable to [illegible] rs because of age and constitutional susceptibility.

[illegible] f the Committee on the Biological Effects of Ioniziung Radiations [illegible] nittee) will not be available for several weeks, but a completed [illegible] een submitted to the Office of Radiation Programs of the [illegible] Agency, which supported the study.

[illegible] ting within the Division of Medical Sciences of the Research [illegible] Sciences, was charged with bringing up to date a study by the [illegible] The report does not make recommendations for the purpose of [illegible] r presents scientific judgments based on the evaluation of available [illegible] a.

[illegible] oint out the Table of Contents of the latest BEIR report and then [illegible] y and conclusions of the report.

[illegible] of the report naturally starts out with a preface, lists the committee [illegible] s the summary and conclusions. Chapter I, the introduction; [illegible] ientific principles in analysis of radiation effects; Chapter III is a [illegible] tes of radiation exposure in the United States; Chapter IV is on [illegible] on somatic effects - cancer; Chapter VI, somatic effects - other [illegible] ossary and a list of the meetings of the Committee.

BEIR REPORT 1979

SUMMARY AND CONCLUSIONS

This report is intended to bring up to date the report of the Committee on the Biological Effects of Ionizing Radiations issued in 1972. In carrying out this intent, we have concentrated primarily on the long-term somatic and genetic risks to people exposed to radiation at low doses--the condition of principal concern with respect to risks to large population groups.

The major contributors of the ionizing radiation to which the general population is exposed continue to be natural background (with a whole-body dose of about 100 mrems/yr) and medical applications of radiation (which contribute similar doses to various tissues of the body). For a given person, the dose from natural background varies with altitude and geographic location, as well as with living habits. Workers in nuclear and other industrial facilities in which radioactive material or x-ray equipment is used are occupationally exposed to radiation that may exceed background severalfold, and the number of such workers is increasing.

The Committee cautions that the risk estimates presented here should in no way be interpreted as precise numerical expectations. They are based on incomplete data and involve a large degree of uncertainty, especially when applied to interpretation of health effects of low doses. These estimates may well change as new information becomes available. Whatever the magnitude of these risks to society and to the individuals exposed, they must be kept in perspective if society is to derive benefits from the use of ionizing radiation. The Committee has no responsibility to recommend regulatory limits nor does it address issues of cost-benefit involving the use of ionizing radiation. These issues are beyond the scope of the task or expertise of this Committee.

RISK OF SOMATIC EFFECTS FROM RADIATION

Evidence indicates that cancers arising in a variety of organs and tissues are the principal late somatic effects of radiation exposure. Organs and tissues differ greatly in their susceptibility to cancer induction by radiation. Induction of leukemia by radiation stands out because of the natural rarity of the disease, the relative ease of its induction by radiation, and its short latent period. When the total risk of radiation-induced malignancies is considered, however, it is clear that solid tumors such as breast, thyroid and lung cancers rather than leukemia are the dominant forms of cancer risk.

The Committee recognizes that information from human data is highly uncertain with regard to the shapes of dose-response curves for cancer induction by radiation, especially at low doses. Estimates of risk at low doses may depend more on what is assumed about the mathematical form of the dose-response function than on the data themselves. For most calculations of estimated cancer risk at low doses, the Committee has used the linear no-threshold hypothesis (effect proportional to dose). The Committee recognizes that some experimental and human data, as well as theoretical considerations, suggest that, for exposure to low-LET radiation at low doses, most cancer risk estimates based on the linear hypothesis are high and should not be regarded as more than upper limits of risk. (Low-LET is radiation characteristic of x rays and gamma rays. High-LET is radiation characteristic of fast protons and neutrons, e.g., alpha particles.) For exposure to high-LET radiation, the risk estimates derived for low doses are less likely to be overestimates of risk and may, in fact, be underestimates.

There is now considerable evidence from human studies that age, both at exposure to radiation and at appearance of cancer, can be a major determinant of radiation-induced cancer risk. For this reason, the Committee recommends that risk be expressed in age-specific terms wherever possible.

The Committee's most difficult task has been to reach a consensus on how to estimate the carcinogenic risk of low dose, low-LET radiation. (There were unresolvable differences among the members of the Subcommittee on Somatic Effects concerning the methods of interpretation of human data to arrive at an estimate of health risks of low-dose, low-LET whole-body radiation exposure. As a result of these differences in the interpretation of human data, a dissenting minority view has been prepared; it is presented as an addendum to Section 3 of Chapter V, "Estimating the Total Cancer Risk of Low-Dose, Low-LET Whole-Body-Radiation.") It was recognized early that there is no truly adequate or generally acceptable scientific basis for such estimation, but that policy or regulatory decisions require a position on the estimation of risk. In resolving the differing positions taken by Committee members, the Committee came to the judgment that emphasis should be placed, not only on specific numerical estimates, but also on the assumptions, procedures and uncertainties involved in the quantitative risk estimation. For the lifetime risk of cancer incidence induced by low LET radiation for a single whole-body exposure to 10 rad the range of increased risk is estimated to be 1.2 to 4.5 percent above the naturally occurring rate for females and 0.8 percent to 3.2 percent for males. The corresponding estimated increase in mortality from a single 10 rad exposure is 0.5 percent to 2.7 percent for females and 0.4 percent to 2.0 percent for males. The risk of cancer incidence induced from continuous lifetime exposure to 1 rad per year ranges from an 8.4 percent to 32.6 percent increase for females and 5.2 percent to 17.9 percent for males. The corresponding mortality estimates are 16.9 percent for females and 2.7 percent for males. These ranges of risk estimates reflect various factors of uncertainty which are described in detail.

We do not know whether dose rates of gamma or x rays of about 100 mrad/yr are detrimental to exposed people. Any detrimental somatic effects will be masked by environmental or other factors that produce the same types of effects on the health of exposed people as does ionizing radiation. It is unlikely that carcinogenic and teratogenic effects of doses of low-LET radiation administered at this dose rate will be demonstrated in the foreseeable future. For larger doses, as from high-dose lifetime occupational exposure, a discernable carcinogenic effect could be manifest.

Reductions in dose rate may decrease the observed radiation effect per unit dose, particularly for low-LET radiation. There appear to be mechanisms, however, especially pertaining to exposure to high-LET radiation, that increase the observed effect per unit dose when the dose rate is reduced. The Committee recognizes that dose-rate effects may be a source of uncertainty in risk estimates for cancer induction, but believes that available information from human data is insufficient to permit appropriate corrections.

A notable development since the 1972 BEIR report is the increasing recognition that there are human genotypes that confer both increased cancer risk and increased susceptibility to DNA damage after exposure to carcinogenic agents, including ionizing radiation. The role of constitutional susceptibility to cancer induction is not well enough understood to be used as a factor for modifying risk estimates for radiation carcinogenesis. Inasmuch as the risk estimates developed for this report are averages for large populations that presumably include many genotypes, it is unlikely that these risk estimates would be notably altered if data representing very small subsets of abnormally radiosensitive persons could be recognized and excluded from the calculations. However, where there are large subsets of this type--for example, in the case of breast cancer, with females highly sensitive in comparison with males--the risk is calculated separately for the sensitive group. If other substantial population subsets can be identified in the future as being at substantially greater risk of radiation carcinogenesis, their risk will also require separate consideration.

The developmental effects of radiation on the embryo and fetus are strongly related to the stage at which exposure occurs. Most information on such effects is derived from laboratory animal studies, but the human data are sufficient to indicate qualitative correspondence for developmentally equivalent stages. In laboratory animals, some developmental abnormalities have been observed at doses below 10 rads. Atomic-bomb data for Hiroshima indicate that microcephaly was induced by acute air doses in the range of 1-9 kerma (average fetal dose, gamma rays at 1.3 rads and neutron rays at 0.1 rad) received during the sensitive period. Because a given gross malformation or functional impairment probably results from damage to more than a single target, the existence of a threshold radiation dose below which that effect is not observed may be predicted. There is evidence of such thresholds, but they vary widely, depending on the abnormality. Observed dose-rate effects may also be the result of the multitarget causation of these abnormalities. Furthermore, exposure protraction can reduce dose effectiveness by decreasing to below the threshold the portion of the dose received during a particular sensitive period. Where a developmental effect is measured in terms of damage to individual cells, as in oocyte-killing, a threshold for this effect may be absent.

For somatic effects other than cancer and developmental effects (e.g., cataracts, aging, and infertility) considered in this report, the available data do not suggest an increased risk with low-dose exposure of human populations.

RISK OF GENETIC EFFECTS FROM RADIATION

Because of the almost complete absence of human data on radiation-induced transmitted genetic effects and because of the likelihood that such data will not soon be forthcoming, estimation of genetic risks must be based on laboratory animal data. This entails the uncertainty of extrapolation from the laboratory mouse to man. However, there is information on the nature of the basic lesions, which are believed to be similar in all organisms; and several physical and biologic variables of radiation mutagenesis have been experimentally explored. For these reasons, some of the uncertainties encountered in the evaluation of somatic effects are absent in the estimation of genetic risk. Human data have been used for estimation of genetic effects resulting from gross chromosomal aberrations.

In evaluating genetic risks, the Committee has considered new data on the incidence of genetic disease in human populations. In addition, recent theories of curvilinear dose-response functions and information on dose-rate effects for radiation of different qualities have been reviewed. For low doses and dose rates, a linear extrapolation from fractionated-dose and low-dose-rate laboratory mouse data continues to constitute the basis for estimating genetic risk to the general population. The Committee's genetic-risk estimates are expressed as effects per generation per rem, with appropriate corrections for special situations, such as exposures of small groups to high-LET radiation.

Although the Committee used a new method of estimating genetic effects expressed in the first generation, the present estimates of genetic effects are not notably different from those of the 1972 BEIR report. In the first generation, it is estimated that 1 rem of parental exposure throughout the general population will result in an increase of 5-75 additional serious genetic disorders per million liveborn offspring. Such an exposure of 1 rem received in each generation is estimated to result, at genetic equilibrium, in an increase of 60-1,100 serious genetic disorders per million liveborn offspring.

The ranges of the risk estimates given in the preceding paragraph emphasize the limitations of current understanding of genetic effects of radiation on human populations. Within this range of uncertainty, however, the risk is nevertheless small in relation to current estimates of the incidence of serious human disorders of genetic origin--about 107,000 per million liveborn offspring.

GENERAL CONCLUSIONS

Genetic-risk estimates have been restricted to persons with induced disorders judged to cause a serious handicap at some time during life. Even in that category, some disorders are obviously more important than others. In contrast with induced somatic effects, which occur only in the persons exposed, induced genetic disorders occur in descendents of exposed persons and can often be transmitted to many future generations. Somatic-risk estimates are concerned with induced cancers. Although most of these are fatal, some, such as thyroid cancer, are usually curable, but entail the risk and costs of medical followup care. Somatic effects also include developmental abnormalities of varied severity caused by fetal or embryonic exposure. It is important to realize that evaluation of comparisons of genetic and somatic effects must take into account ethical or socioeconomic judgments that are beyond the scope of the Committee's responsibility. As an example of the problem, it is extremely difficult to compare the societal impact of a cancer with that of a serious genetic disorder.

These conclusions concerning genetic risks have been strengthened by new methods and data obtained since the 1972 BEIR report, but the resulting risk estimates are nearly the same as those presented in that report. The conclusions concerning somatic risks have added to and extended the earlier estimates, but in general the present Committee's conclusions are not in fundamental disagreement with those presented in the 1972 report.

ALARA -- RADIATION RISKS and the NEED to KEEP EXPOSURES "AS LOW AS REASONABLY ACHIEVABLE"

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I am glad to have this opportunity to attend this important Annual National Conference on Radiation Control and to discuss current concepts of radiation risk and the philosophy of maintaining exposures "as low as reasonably achievable (ALARA)." First, I should make it clear that as a staff health physicist with a regulatory agency I am sent here to communicate individual opinions and information, and my remarks will not always necessarily reflect official NRC policies. I am also sent here to learn from you, in return, about any of your own problems in obtaining compliance with the ALARA philosophy--particularly in cases where you have attempted to utilize ALARA guidance published by the NRC.

You have already heard from a distinguished representative of the National Academy of Sciences about the recent review of basic radiobiological effects and basic risk estimates (BEIR III). Next, you will hear about the findings and recommendations of the Interagency Task Force on Radiation Exposure, which will further summarize the status of our knowledge and the organization of Federal efforts to monitor and control radiation exposures and their effects. Thus, in this talk I will elaborate on the concepts of risk implied by our basic scientific information, since these concepts are, in turn, basic to implementation of our radiation control programs. I hope that my talk will also provide some further thoughts that may be useful in explaining radiation risks to workers and the public, as well as to others who are involved in the legislation, organization, or direction of radiation control programs. In the limited time remaining, I will also summarize current trends in occupational health standards at the Nuclear Regulatory Commission.

Since this audience is knowledgeable regarding magnitudes of exposures from the various sources contributing to human radiation exposure, I will not dwell on this subject in any detail. However, I would like you to briefly examine Tables 1 and 2 to place in perspective the wide range of magnitudes over which these exposures do range.

Table 1. Annual per capita doses from normal exposure to natural sources of radiation (in mrad)

	Gonads	Whole lung	Bone-lining cells	Red bone marrow
External irradiation				
Cosmic rays	28	28	28	28
Terrestrial radiation	32	32	32	32
Internal irradiation				
Potassium-40	15	17	15	27
Radon-222 (W/daughters)	0.2	30	0.3	0.3
Other nuclides	2	5.5	9.1	4
Total	78	110	84	92

From UNSCEAR, 1977, p. 11 (4).

Table 2. Global dose commitments from various radiation sources

Source of Exposure	Global dose commitment (days)[a]
1-year exposure to natural sources	365
1-year of commercial air travel	0.4
Use of 1 year's production of phosphate fertilizers at the present production rate	0.04
1-year global production of electric energy by coal-fired power plants at the present global installed capacity (10^6 MW(e))	0.02
1-year exposure to radiation-emitting consumer products	3
1-year production of nuclear power at the present global installed capacity (8 x 10^4 MW(e))	0.6
1-year of nuclear explosions averaged over the period 1951-1976	30
1-year's use of radiation in medical diagnosis	70

[a] The global dose commitment is expressed as the duration of exposure of the world population to natural radiation that would cause the same dose commitment. The occupational contribution is included.

UNSCEAR, 1977, p. 16 (4)

I would now like to focus for a moment on the magnitudes of occupational exposure. Occupational radiation exposure contributes the major part of the collective person-rem population dose from the nuclear industry. These exposures tend to have a characteristic frequency distribution that approximates the log-normal shape over an annual dose range per individual of up to 1 rem or more (3,4). Figure 1 shows a comparison of these distributions for several industries for the year 1974. This figure shows the effect of the lifetime average control limit in keeping more than 98 to 99 percent of the worker populations less than 5 rem in 1 year (note the upward curvature of the cumulative frequency distribution from the "natural" line on the probability-versus-log dose scale).

Also, the effect of maintaining exposures ALARA can be observed from the linear portion of the cumulative plot. In Figure 2, the projection of the linear portions of the plots of Figure 1 into the low-dose range illustrates a "pressure" to keep the exposures of most monitored workers far below the annual limits. (A discussion of errors in dosimetry is beyond the scope of this paper. However, the reader may note that the "law of large numbers" causes the points over a wide region to fall on a smooth line, implying better precision in average population annual doses than might be expected on the bases of known uncertainties in individual dosimeter readings.) In fact, the median exposures are so low that they can only be estimated by extrapolation of the measurable doses into the low-dose range. Extrapolated medians are only 2.7 mrem for all monitored reactor workers, 15 mrem for fuel processing and recovery and byproduct manufacturing, 4.3 mrem for industrial radiography, and 8.4 mrem for all licensees reporting. When only those workers who had positive annual readings are included in the plot, the shape of the distribution is still linear in the ≤ 1-rem range, and concave upward above, but the median for all monitored workers with positive readings becomes 152 mrem, still only about 3 percent of the 5-rem annual limit.

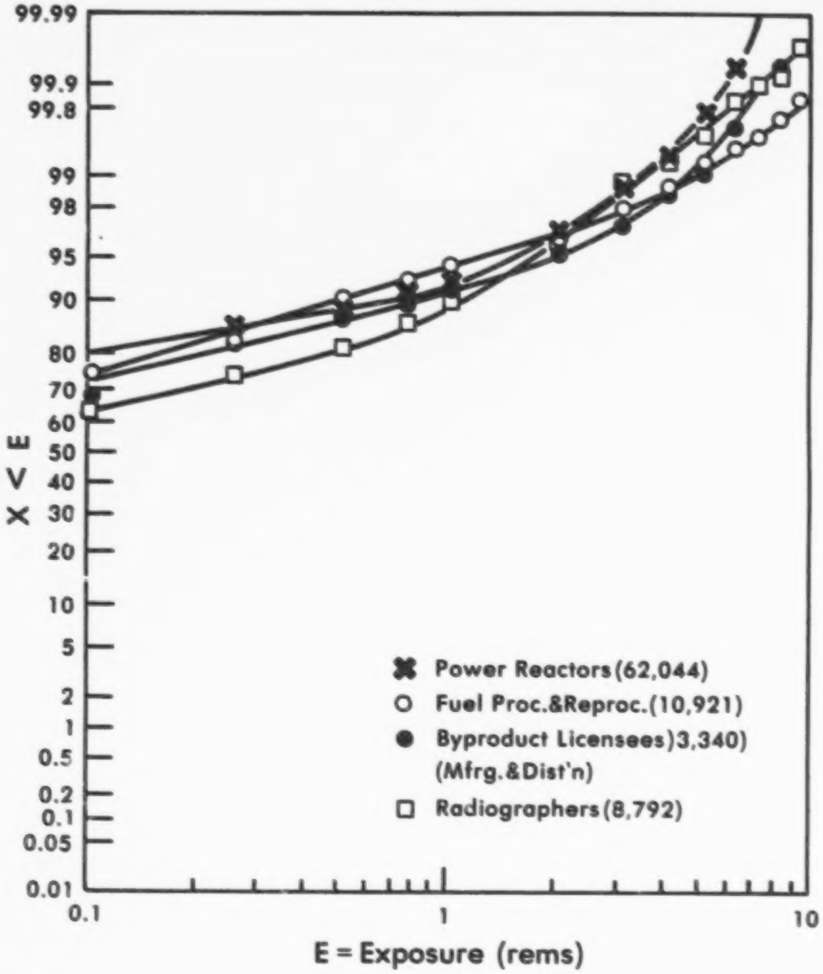

Figure 1

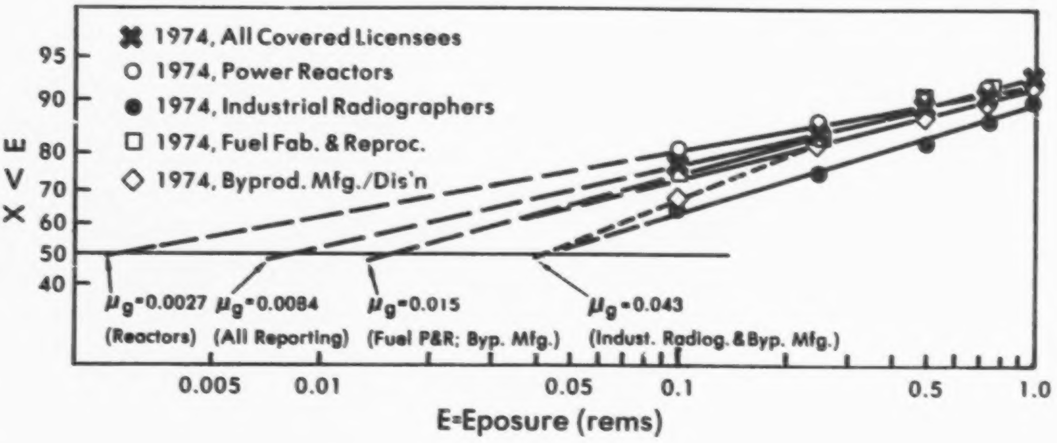

Figure 2

I suggest that cumulative frequency distributions could be examined State by State in this manner, as well as industry by industry, to obtain an assessment of trends in the effectiveness of radiation control programs over time. Also, I urge that frequency distributions of exposures and their parameters be examined both with, as well as without, the including of persons who have been monitored, but whose recorded exposures are "negligible" or zero. This practice, as well as the examination of criteria for providing personnel dosimetry, can avoid false impressions because of inappropriate presentation of statistical data.

For example, consider a worker population where additional protection is provided for the lower dose portion of a population, but the few workers receiving greater than 1 rem still are maintained only at the same level of protection. Although there would be a somewhat increased level of protection, a too cursory examination of the plot showing only the distribution of positive readings would appear to indicate an increase in the average and median dose of this (somewhat depleted) group. All relevant data, including numbers of workers monitored and any changes in monitoring practice, must be examined to obtain an accurate picture of exposure trends.

We are all familiar with the concept of risk as a chance (or probability) that an adverse health effect or death may occur as a result of a given radiation exposure. Before we discuss this in more detail, it would be useful to select some estimates of the risk of cancer per unit of radiation dose, under the simplified assumptions of a linear dose-response relationship at low doses that has no threshold, and passes through the origin. For our purposes, we will adopt the estimates of Gotchy (5), which are based on 1972 BEIR report values (6). The values of Gotchy are shown in Table 3, translated into a more common terminology of chance. These risk factors are believed to be conservative (on the safe side) for the ranges of dose and dose rates encountered in the nuclear industry. These factors are also believed consistent with the conservative estimates of risk in the recently released BEIR III report (7), which has just been discussed by the previous speaker. The NRC staff and other participating agencies have used similar risk factors in the preliminary estimates of population effects from the Three Mile Island accident (8).

Table 3. Maximum cancer deaths and average life shortening for 1 rem of radiation dose[a]

Type of cancer	Chances of cancer death per rem	Average shortening of life
Leukemia	23 in a million	0.20 days
Lung	25 in a million	0.14 days
Stomach	12 in a million	0.065 days
Alimentary canal	4 in a million	0.0073 days
Pancreas	4 in a million	0.0073 days
Breast	29 in a million	0.062 days
Bone	5 in a million	0.029 days
Thyroid	10 in a million	0.0062 days
All other	20 in a million	0.11 days
Total	13 in 100,000	0.63 days

[a] Revised to give the maximum chances of cancer and life shortening to be expected by an individual worker.

From R.L. Gotchy, Health Phys 35:563-565 (1978) (5).

Since there has been some confusion in the press on this matter, I would like to make it clear that I have personally rejected, (9,10) as have a number of others (11-18) whom I believe are eminently qualified to analyze epidemiological data, the claims of Mancuso, Stewart and Kneale (19-20) that the Hanford data show cancers that can be attributed to occupational exposure. I also wish to state my personal rejection of other recent claims that risks of radiation exposure at low dose levels have been validly proven or indicated to exceed the (conservative) estimates previously obtained by the eminent BEIR (6) and UNSCEAR (4) committtees. I will not dwell on this further, but refer the audience to the references included in this paper, as well as the recent BEIR III report (7).

I will also not discuss other radiation-induced health risks--which include genetic, teratogenetic, and other diseases--but for the purposes of this discussion will state that I do not believe that total health effects integrated over all future time would exceed by more than a factor of about 3 the health effects resulting from radiation-induced cancer (4,6,7,21).

Now that we have some initial ideas of the general magnitudes of radiation exposure and risk, I would like to present some concepts of the chance nature of radiation risks and their dependence on radiation dose. I believe that an understanding of the chance nature of radiation-induced diseases is necessary both for those of us who work professionally developing and implementing radiation protection programs, and for other members of the public and our government representatives who must determine levels of acceptable risk and the cost-benefit relationships that ultimately may determine which exposures are indeed ALARA. I hope that the following discussion of the chance nature of some radiobiological effects will be helpful in promoting this understanding, and will be translatable in simple terms to members of the public.

Many health risks of radiation are now believed to result from random (chance) interactions between radiation and biochemical molecules in the gene structures of somatic cells (functional cells of organs), or in genetic cells (cells that generate spermatozoa and ova and determine the inherited traits of new individuals). This means that the effects of low-level radiation exposure are stochastic (they have a chance of occurring that depends on the time distribution of radiation exposure and that varies with time after radiation exposure is initiated). The chance of an effect occurring in a particular organ or tissue also depends on the total amount of radiation dose received, the rate at which it is delivered, the type and quantum energy of the ionizing radiation, the tissue and species in question, the age range over which the dose is received, concomitant exposure to other environmental agents (including oxygen level and temperature), and other factors. Thus, the probability of an effect varies with many factors, but in a given situation always increases in some manner with increasing dose at low dose levels. There is no "threshold" dose below which the probability of an effect is absolutely zero. This has been the belief of most knowledgeable scientists for at least 30 years, although there has been some disagreement over the shape of the dose-response relationship (above zero threshold) that should be assumed in order to avoid underestimating risks under the practical range of human exposure conditions.

There are some easy ways to develop a mental picture of the probabilistic (or chance) nature of low-level radiation effects--and thus a better understanding of radiation risks. First, it has been well known for about 50 years or more that the interactions of x or gamma rays (and similarly neutrons) occur by transfer of energy primarily in discrete interactions with the electrons or nuclei of matter. These phenomena--although extremely complex in detail--can be visualized by the layman as discrete "hits" for purposes of understanding the important biological effects of radiation.

Further, when these hits deposit energy in living systems, significant or harmful somatic or genetic changes (called "mutations") occur only when "radiation hits" produce certain reactive chemical species very close to tiny and specific targets in the genetic material (of certain types of cells (22)). There is considerable evidence suggesting that cancer, and perhaps many genetic effects, can not develop unless two (or more) (4,22) chemical changes occur in nearby gene sites, often in the proper order (22). The second change may not occur for a particular cell, unless a first genetic change has been produced by a previous radiation quantum "hit" (or some specific chemical mutagen). Certain chemical agents (called "carcinogens") can produce the same cancerous mutations caused by radiation--sometimes together with other agents (called "promoters," "initiators," or "co-carcinogens") that change only one of the two (or more) gene sites.

A simplified model can be visualized for understanding the chance nature of the appearance of resulting diseases caused by these physical and chemical events. Gamma rays (like x rays and other radiations) are always emitted in discrete packets of energy, like bullets. Imagine these bullets being aimed by a nervous rifleman at two small targets, several hundred yards away. One of these targets is a golf ball hanging from a tree by a flexible rubber band. The other target is a baseball hanging by an inflexible string. The baseball is hanging behind the golf ball, blocking a hole in the tree. In order to give the tree cancer, the golf ball must be knocked into a hole in the trunk of the tree, where it will stick and stay once it gets in. However, the baseball is blocking the hole. Thus, the first hit must break the string holding the baseball. Otherwise, even if the golf ball is hit and heads toward the hole, it will hit the baseball, deflect in some direction, and eventually swing back to rest in the same equilibrium position (analogous to biological "repair" of the initial damage). Thus, two hits must occur and in the proper order. Each hit would be a rare event for a nervous rifleman at such long distances. It would be a very unlucky tree that could be hit twice in the right order and get cancer, unless the number of bullets aimed began to reach some enormous number. Even so, for two or more bullets, one can easily see that the chances of tree cancer are not zero, and increase with an increasing exposure to bullets. The statistical nature of radiation effects in humans at low-dose levels is similar to the bullet-golf ball-baseball analogy just described.

I can give a personal example of my own experience, showing how rare the hits must be that produce cancer (or other health effects). In the first half of the 1950's, I received about 20 R (20,000 millirem) of exposure--about the highest lifetime dose that would actually be received by most "radiation workers" (23) under the radiation safety programs established in accord with our ALARA philosophy. The latent periods for appearance of many radiation-produced cancers, or for clinical expression of the probability of cancer appearance, have largely passed. Yet, although I believe some small probability remains, no cancers or observable health effects have yet appeared. My wife and I also conceived two more children after most of my exposure was received, and they have now grown into a healthy 22-year-old female and a healthy 21-year-old male.

An exposure of 20 R, primarily gamma radiation, can be shown from basic physical principles to mean that more than 20 billion gamma photons (bullets) have entered each square centimeter of my body. Most of this was "whole body" irradiation, and thus about 2000 billion gamma-ray bullets have entered my body. These gamma rays were in an energy range such that the majority of them interacted with molecules of my body. Each hit knocked out thousands of electrons and caused thousands of excited molecules, each capable of producing biochemical reactions. Therefore, the 20-R exposure I received must have resulted in millions of billions of chemical reactions in my body. Since I did not feel any of them, and no cancers have appeared so far in my body (nor in the bodies of other workers who have been similarly exposed (10,23)), some interesting conclusions can be drawn:

(a) the effects of low exposures to radiation must be chance effects--there is no certainty an effect will occur, only some small probability per incident photon;

(b) the probability that a single gamma photon (or a small number) will cause a biologically unrepairable and medically important effect is extremely small--it is a rare event, involving extremely small and/or extremely rare targets (the probability of a single photon entering the body interacting in a clinically important way being less than one in a million-billion); and

(c) because of the chance events described above, the probability of an effect (no matter how small) may be expected to increase in a monotonic way with increasing dose, for doses greater than zero (or at least above 2 photons/cm^2, or one billionth of a roentgen).

However, the shape of these monotone increasing dose-response curves, at observable experimental or human levels of risk, has been found to vary with many factors (4,6,7). A mathematical formulation of the phenomena of chance "hits" alone can be shown to result in a variety of monotone increasing dose-response shapes, depending on the relative magnitudes of some of these factors (24). A further discussion of these and other factors would be too complex and detailed for our purposes here. It is sufficient to say that for radiation protection purposes, various scientific bodies have over the past 30 or more years attempted to develop radiation protection standards based on estimated upper bounds to the somatic and genetic risks. These upper bounds have been generally estimated using linear, nonthreshold extrapolations of risk down to zero dose, from determined risks at high doses and dose rates. The extent to which such a linear extrapolation may actually overestimate the risks of radiation exposure will be discussed in a forthcoming revised publication of Reference 7.

The chance nature of radiation effects, as just described, implies that any further reduction of radiation exposures--whether to one individual or to a population--will result in lower risks. This is true no matter how low the exposure rates may already be. Thus, at some point in a given situation, the question often arises whether the cost, or sacrifice, required to further lower exposures could reduce health risks--or increase human benefits--to a greater degree if the cost or effort were applied to some other endeavor (such as health research, or greater product safety).

Thus, the above discussion gives the reasons why the NRC has adopted the philosophy of keeping occupational exposures "as low as reasonably achievable" and has made wide use of the acronym ALARA in its regulations and guides as a reminder of this philosophy (25-31). The philosophy has evolved (2) over many years of regulatory experience from similar admonitions by the National Council on Radiation Protection and Measurements (NCRP) (32).

> "The NCRP recommendations are centered on the principle that the 'lowest practicable' radiation level is the fundamental basis for establishing radiation standards, with due consideration being given to the risks and benefits associated with a given radiation exposure (NCRP, 1971)."

Keywords in this philosophy of ALARA are "low " and "reasonably." The word "low" always means some exposure or dose below specified limits. How far below the limits the actual dose may be depends on what may be reasonably achievable. No exact formula has been given, and probably in most cases can never be given, to define "reasonably achievable." Economic and health benefits can be set forth and examined, and estimates of their value can be made, or at least bracketed into ranges (21,33), so that each use of radioactive material, or other agent carrying risk, may be designed to be achieved with the lowest possible dose that would allow the achievement of the (greater) benefit.

The NRC and other agencies have long searched for and developed "ALARA criteria" and are still doing so. The value of $1,000 per man-rem has at times been proposed as a guideline for the expenditure of funds for additional equipment to reduce exposure at reactor installations below regulatory limits. (The value of $1,000 per man-rem has also been used as interim guidance for cost-benefit analyses required by the provisions of 10 CFR Part 50 Appendix I.) Such a value can be useful for problems of a certain kind, and within a restricted range of doses. However, the problem of establishing a monetary value for an incremental reduction in man-rem (either for an individual worker or for a population) is not a linear problem, just as the dose-response relationship under consideration is probably not actually linear (4,7,21,24). Thus, no single monetary value is applicable in all cases, and in some instances a radiation protection program must be designed to keep exposures ALARA on the basis of an economic and social judgment considering all of the factors peculiar to the industry and its operations and products.

Despite the need for judgment in determining radiation protection programs and equipment for ALARA exposures, there is still the need to maintain established limits of occupational (and public) exposure within values generically determined to represent some upper limit of "acceptable" risk (32). Thus, no matter what, or how great, the benefits of a certain product or service, the product or service can not be allowed to be made or distributed if it requires exposures (individual or collective population) that exceed any regulatory or recommended limits (26,32). (Any override of this principle would require a public evaluation that some emergency need of the population justified a higher acceptable risk under that particular situation--the current limits have been judged on current societal conditions under which the known beneficial uses of radiation occur.) Thus, any exposure above limits can only be considered "unreasonable," unplanned, or accidental, and are not allowable under regulatory requirements on ALARA philosophy.

I have previously shown that the above considerations, as well as the continuing increase in products and services utilizing radiation sources, lead to the conclusion that individual products, services, and uses of radiation must eventually be divided into quantized categories of benefit, each having its own limit of population and individual exposure, with limits that continually reduce in value in such a way that total population exposures in all categories do not ultimately exceed established limits of population exposure (21,33). I have also shown--using consumer products containing radioactivity as an example--that it is possible to develop a matrix of exposure limits and an accounting system, and that it is possible to meet ALARA exposure conditions within the appropriate limit of a particular product (21,33). I believe that the same would be true--with developing science and technology--in regard to all sources of radiation (and indeed other chemical or physical agents of risk) that have been found to be of human benefit and industrial viability.

Although I do not believe that any agency has seriously considered developing a matrix of exposure limits as proposed in my papers (21,33) there is a trend toward lowering the occupational and public exposure limits that may be attributable in part to the realization that the number of sources of exposure to radiation and other agents is increasing, and that some additional conservatism is necessary to limit risks. The current staff opinion in NRC, taking into account trends in policy development within the Environmental Protection Agency and other government agencies, has been reviewed by Goller (1) and leads to the expectation that:

(a) An absolute occupational exposure limit of 5 rem per year is likely to be adopted, with a 3 rem per quarter limit; the cumulative lifetime exposure limit of 5(N-18) rem will be eliminated. Thus, exposures of up to 12 rem in any 1 year will no longer be allowed.

(b) Individual licensees are likely to be required to develop individual occupational ALARA programs that are inspectable and enforceable. These programs will be specific for each licensee's particular operations.

It is important, as uses of radiation increase, to maintain control of the total person-rem (total of all exposures received by all persons) since the probability (and number) of harmful effects increases with the total person-rem, whether the dose-response relationship is linear, sub-linear, or supra-linear (1). Under the linear assumption, if the exposure of a few workers is reduced by hiring more part-time workers and spreading the dose over many persons, the chances of cancer (for example) remain the same for the same number of person-rem. If the risk curve rises faster than the linear dose-response curve used to develop radiation protection standards (i.e., "supralinearity"), then the spreading of dose among more persons would actually increase the number of cases of cancer likely to occur, for the same number of person-rems. Few scientists believe that supralinearity is likely at low dose levels to produce risks that appreciably exceed those estimated on the basis of the linear extrapolations in use by the reputable standards and review agencies. In fact, the more reputable radiobiologists tend to believe that the linear extrapolation overestimates risks at low doses and low dose rates, under usual conditions of exposure (7). Nevertheless, decreasing both individual and collective exposures will always reduce the total amount of risk. It is likely that future radiation protection standards will limit both types of exposure (individual and collective) for radiation workers, and also probably for the public.

SUMMARY

In summary, effects of low-level radiation are probabilistic in nature, and they consist mostly of cancer risks and, for those who have not yet borne offspring, teratogenic and genetic effects to future generations. A lifetime dose of 20 rems would produce a risk estimated to be no greater than about 26 chances in 10,000 of dying of cancer (slightly greater than that of dying in a fire), and about 50 in 10,000 of contracting cancer. The risk of a deleterious genetic effect in some future generation is about the same (or lower) as that of dying of cancer, for those who have not yet had their children. Any health effects other than cancer (which have not been demonstrated at low-dose levels) are not likely to occur with frequency exceeding that of cancer. However, the risks of radiation are chance effects that increase in probability as radiation exposure increases, and they should thus be kept ALARA. Also, the risks of health effects following accidental exposures can be very high, and the incidence of any such accidents should be maintained ALARA through better equipment, training, and procedure. NRC guides have been published in Category 8 to assist in keeping exposures ALARA in nuclear power reactor installations and medical institutions. Further development of ALARA guidance and standards is underway at NRC and in other agencies and committees. We would like you to continue to comment on these developments and to provide your own input toward the promulgation and implementation of both safe and reasonable radiation protection programs at the Federal, State, and local levels.

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FINDINGS and RECOMMENDATIONS of the INTERAGENCY TASK FORCE on RADIATON EXPOSURE

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I appreciate your giving me the opportunity today to speak to you about the work of the Task Force. I will outline the contents of the reports and then attempt to answer questions.

On May 9, 1978, the White House sent a memorandum to four Federal agencies, directing them to develop a coordinated program in response to growing concern about the effects of radiation exposure. The Secretary of HEW, Joseph A. Califano, Jr., was given the lead on the project. He delegated the task to Mr. Peter Libassi, the General Counsel. The Secretary directed Mr. Libassi to work closely with other Public Health Service agencies within HEW, as well as with the Center for Disease Control in Atlanta, Georgia.

Mr. Libassi convened an interagency task force composed of officials from the Departments of Defense, Energy, and Labor, the Environmental Protection Agency, the Nuclear Regulatory Commission, the Veterans Administration, and HEW. Five work groups were established, under the Task Force; each composed of staff representatives from the Task Force agencies. The work groups produced five reports, each on a different aspect of radiation policy. A sixth report, on institutional arrangements or rearrangements within the Federal Government, was drafted by HEW staff after discussions by the Task Force and was reviewed by Task Force members. All of these reports have been released for public comment, including the last--the institutional rearrangements report. The public comment period expires May 15.

I would like to point out that these papers do not represent the definitive views of HEW or the other agencies on the Task Force. They have been reviewed and discussed extensively by the agency representatives to the Task Force, but they have not yet been formally cleared by the heads of the agencies in all cases. The final views of the Task Force will be presented in the report to the White House. That report is expected to go to the White House by mid-June.

Before discussing the findings of the work groups, I would like to mention an important aspect of the proceedings of the Task Force. Currently, among members of the public there is a great deal of skepticism about the actions and intentions of Federal agencies. From the beginning of the project, there was concern about keeping the decisionmaking process open to groups and individuals outside the Federal Government. We have tried to be responsive to the concerns of these groups and to keep them fully informed about our work. As a result, a number of informal meetings have been held with scientists of varying viewpoints, public interest and environmental groups, representatives from State radiation control, representatives of the nuclear power industry, the medical professions, labor unions, and veterans' organizations. In addition, we have had many meetings with members of Congress and their staff. Public comment on the reports has been solicited from these groups and from others interested in radiation issues. The work papers and the public comments will form the basis for the Task Force report to the White House.

The work groups focused on five different subjects:

1. The biologic effects of ionizing subjects;

2. Legal restrictions on the access of health researchers to records they need to complete their work;

3. Reduction of radiation exposures;

4. Delivery of care and benefits to those injured by exposure to radiation; and

5. Public information.

I am not a scientist, so I hope you will bear with me as I outline the findings of the science work group. This group, which was chaired by Dr. Clark Heath, an epidemiologist from the Center for Disease Control, reviewed the numerous published studies that provide information about the health effects of ionizing radiation. The group also compiled a list of current research conducted or sponsored by Federal agencies, and recommended areas for future study.

Although the science work group report discusses acute somatic effects, genetic effects, and developmental effects, it focuses upon the delayed somatic effects--basically, various forms of cancer produced by low doses of radiation. The report reviews epidemiological studies of groups exposed to radiation from atomic weapons, from medical sources, and from sources encountered in the workplace. It presents findings that have been confirmed in several studies, as well as findings that are more problematic. It also notes the methodological problems--ranging from inadequate records (poor dosimetry, no data on confounding variables) to insufficient sample size--that hinder researchers tracing effects produced by very low doses.

The report examines the recent controversy caused by four studies suggesting that the effects of radiation at low doses may be more extensive than has been thought. Each of these studies--the study of Hanford workers by Mancuso, Stewart, and Kneale; the study of Portsmouth Naval Shipyard workers by Najarian et al.; the CDC study of veterans exposed to the "Smoky" atmospheric weapons test; and the reanalysis of the Tri-State Medical Exposure Data by Bross--is either incomplete or suffers from other difficulties and uncertainties. While acknowledging that these studies raise important questions about the effects of low-dose radiation, the report concludes that existing studies are simply not sufficient to provide definitive information on the effects of radiation at doses around 5 rem per year or below.

The work group also expressed the view that methodological problems may well preclude scientists from ever obtaining precise information about low-dose effects through epidemiological studies. The most that can be expected is to narrow the areas of uncertainty.

To address methodological problems, the work group recommended improvements in record systems and in linkages between record systems, in order to assist future studies. Information in the records of radiation workers should ideally include radiation exposures from occupational and other sources as well as exposures to other toxic agents. The group was aware that proposals to improve and centralize record systems had been advanced and rejected in the past, but felt that a study of the feasibility and utility of these reforms deserved reconsideration.

The work group also recommended further research in a number of specific areas:

1. epidemiological studies of groups exposed to low doses, provided that initial feasibility studies demonstrate the suitability of the population for long-term study;

2. continued research on human populations that have been exposed to higher levels of radiation;

3. further experimental research examining the effects produced by differing dose rates and by dose fractionation;

4. research to demonstrate the effects of different radionuclides and the various pathways through which they reach human tissue; and

5. studies that provide information on genetic effects and on synergistic effects produced by the interaction of radiation and other agents.

The second work group, the work group on records and privacy, was chaired by Stephen Cole, an attorney in Peter Libassi's office and now Acting Legal Counsel, HEW. This work group, composed of lawyers and scientists from the Task Force agencies, examined legal barriers to health researchers who seek access to records containing personal information about individuals. In recent years, legislatures have erected such barriers out of concern for the privacy of record subjects. Generally, the focus of the concern has not been the use of personal information in health research, but rather the possible misuse of such information by public agencies or private companies in decisions affecting the individual. However, laws have been written broadly enough also to bar or to delay researchers' access to the data. Further, there is legitimate concern about researchers' redisclosure of individually identifiable information to nonresearchers.

The records and privacy work group examined the extent to which legal barriers presently impede access, focusing on Federal records held by the IRS and by the Social Security Administration, which are useful for tracing individuals and linking record systems. The group concluded that the needs of health researchers can be met within existing law, although delays may occur. It recommended a number of administrative and legislative reforms that might ease access for health researchers while providing increased protection to the individual record subject. These reforms would clarify treatment of records under the Privacy Act, remove barriers in the Internal Revenue Code, provide new protections for medical and research records, and extend the national death index to include deaths that occurred before 1979.

The third work group, the reduction work group, faced the formidable task of reviewing all major sources of radiation exposure, estimating the contribution of each to the population dose, and recommending steps that might be taken to reduce unnecessary exposures. Fifty percent of the radiation exposure in the United States comes from background radiation found in our air and soil. The work group concluded that control of these sources was not likely to be cost effective where control is possible at all.

Ninety percent of the remaining, manmade radiation exposures comes from the medical uses of radiation, The work group, therefore, focused on ways to reduce unnecessary exposures in this area, without hindering the usefulness of radiation for diagnosis and treatment of disease. The work group identified several factors leading to excessive use of radiation in the healing arts. The first factor is inadequate clinical judgment by the person who orders the use of radiation. For example, a physician may order an x-ray to protect himself or herself against a malpractice claim or to reassure a patient. Insurance companies require x rays to verify that a procedure was performed. In addition, x rays are used for routine screening purposes without careful examination of their risk relative to their benefit (e.g., hospital admissions or preemployment). Most importantly, scientific data on the "efficacy" of particular procedures are inadequate; that is, researchers have not systematically determined when a procedure assists in diagnosis and when it does not.

Other factors contributing to excessive use of radiation in medicine include inadequate equipment and use of improper techniques by professionals performing radiological procedures.

The work group recommended continuation and expansion of efforts by the Food and Drug Administration's Bureau of Radiological Health--in concert with groups such as the National Council on Radiation Protection and Measurements, professional organizations, and consumer groups--to reduce radiation exposures in the healing arts. Recommendations include development of referral criteria, better education of professionals and of consumers, credentialing of technicians, improvements in radiological equipment, and monitoring of equipment in operation.

Other sources of exposure examined by the work group include technologically enhanced natural radiation--particularly uranium and phosphate mining and milling; the nuclear weapons cycle; the nuclear fuel cycle; and industrial and commercial uses of radiation. Many suggestions for improved controls were made, which I shall not review here. The work group's first recommendation (and one covering all other recommendations) was that the feasibility and cost effectiveness of each of its proposals be examined by the Federal agency with appropriate jurisdiction for implementation of the particular recommendation.

The work group also recommended review of existing exposure standards and an expanded role for State radiation protection programs with increased Federal funding. Among the comments that we have received on this report was a letter from Representative Carter, from Kentucky, who has agreed to sponsor legislation calling for enhanced Federal funding to the States for increased State participation in radiation protection activities, particularly in the areas of medical radiation use and increased environmental monitoring.

The fourth work group, chaired by Donald Gonya, an attorney from Social Security Administration, examined the problem of delivering care and benefits to individuals who may have been injured as a result of exposure to radiation. The focus of concern, when the group began its deliberations, were veterans who were exposed during the atmospheric weapons tests of the 1950's and early 1960's, since there was some evidence of increased cancer incidence among this group. The work group examined the veterans' benefits program, as well as various workers' compenstion programs, which exist to compensate workers injured on the job. A brief review of the tort system as a source of compensation was also provided.

The central problem for compensation and court systems alike is that each system requires a claimant to establish a causal connection between a particular radiation exposure or series of exposures and the claimant's particular injury. This means establishing a connection between two events--exposure and induction of cancer--which may be separated by 10 to 30 years. Further, cancers caused by radiation exposure are identical to cancers caused by other factors. Finally, if current estimates of the amount of cancer produced by radiation are correct, a population irradiated at low doses will suffer only a small increase in cancer incidence, so that in any single case, the cancer is much more likely to have resulted from factors other than radiation. At the same time, some of the cancers in that group will have been caused by radiation. Under current estimates in a population of 10,000 persons, 1,600 persons will die of cancer. If all 10,000 persons are exposed to 1 rem of radiation per person, one additional person will die of cancer--a total of 1,601. The question is: Can these cases of radiation-induced cancer be separated from the others?

Although it seems impossible with current scientific information to perform this feat, it may be possible to narrow the scope of uncertainty about the connection between an exposure and a later occurrence of cancer. Information can be compiled about the connection between particular radionuclides and particular cancers; e.g., iodine-131 and thyroid; radon daughters and lung cancer. The latent period of certain cancers can be estimated within broad limits. The work group recommended that such information be collected in Radiation Disease Guidelines for use in resolving claims. It also recommended that program administrators use these guidelines to develop specific criteria for resolving claims within the framework of their particular program. The group also supported establishment of a central registry of dose information on radiation workers (as did the science work group, after a feasibility study), and annual compilation of all radiation-related claims.

The work group considered proposals for more fundamental changes in existing systems, including alternatives that would eliminate the requirement of proof of causation and alternatives that would relate the amount of the award to the probability of causal connection between the radiation exposure and the subsequent cancer. Because such proposals would be highly overinclusive and thus very expensive under current estimates of disease incidence, the work group did not recommend adoption of any of these alternatives at this time.

The fifth work group, the public information work group, outlined programs that might be undertaken to inform various groups about radiation and its effects. The group recommended that basic messages be developed for the general public and that special efforts be made to reach target groups with more specific messages, including:

1. medical and dental patients and health care personnel,
2. workers exposed on the job, and
3. persons exposed (military and civilian) as a result of the atmospheric weapons tests.

All groups should be informed about what is known about low-dose radiation, what is unknown, the usefulness of some forms of radiation, such as x rays, and the need to avoid unnecessary exposure. Additional messages will be appropriate for the target groups.

In addition, this work group recommended the establishment of a Federal information center or office to coordinate the sources of radiation information that currently exist, but that are spread throughout the Federal Government. The group also recommended the convening of an advisory group of public information specialists and scientists to develop a vocabulary to be used in the messages. Because of the complexity of the subject and the time constraints imposed by the Task Force, it was not appropriate for a task force to develop the messages.

The sixth subject, which was addressed by the Task Force itself rather than in a work group, concerned the institutional arrangements through which the Federal Government manages radiation policy. The objectives to be achieved through institutional change are better coordination among Federal agencies involved in radiation issues, improvements in agency leadership and effectiveness, and increased public confidence in Federal actions. The paper issued by the Task Force recommends certain measures, but presents options on others and seeks public comment on them. It focuses on three areas: Research into the health effects of radiation, radiation protection, and overall coordination of policy development.

Research into the biological effects of ionizing radiation has been dominated for many years by the Department of Energy and its predecessors, the Energy Research and Development Administration (ERDA) and the Atomic Energy Commission (AEC). In fiscal year 1978, DOE funded 63 percent of all Federal research in this area and 78 percent of all human health effects research in this area. Much of current knowledge about radiation is based on research sponsored by DOE.

At the same time, DOE also performs central roles as a developer and promoter of nuclear energy and as an employer, through contractors, of workers exposed to radiation during the production of nuclear weapons. Recently, some members of Congress, various interest groups, and members of the public have expressed concern about DOE's ability to perform all of these roles simultaneously. Last fall, Congress mandated the increased involvement of agencies other than DOE in research on the biological effects of ionizing radiation. It has directed HEW to embark upon a comprehensive radiation research program and to review the research programs of all Federal agencies. Congress has also directed the Nuclear Regulatory Commission and the Environmental Protection Agency, in consultation with HEW, to conduct preliminary studies of epidemiological research on radiation effects.

In light of these developments, the Task Force recommended that an interagency radiation research committee be established to coordinate the development of a comprehensive program of research into the health effects of radiation. This committee would establish general priorities, recommend appropriate locations for research, assure that the research needs of the regulatory agencies were met, and perform other functions. It would be composed of research and regulatory agencies and would be headed by the National Institutes of Health.

The Task Force also recommended expansion of the roles of agencies other than DOE--particularly HEW--in performing research into the biological effects of radiation. The Task Force sought public comment on two ways of accomplishing this result: (1) an expansion of the research budgets of other agencies, resulting in a proportionate reduction in DOE's role, or (2) transfer of some projects from DOE to agencies that perform health research.

On the regulatory side, the Task Force noted the increase within the last decade in the number of regulatory agencies concerned with radiation protection. This development has resulted in a greater need for interagency coordination and cooperation. The Environmental Protection Agency, which is charged with providing guidance to all Federal agencies on radiation protection matters, has been criticized for giving radiation low priority. At the same time, for various reasons, other agencies have not been willing to cooperate with EPA in the development of radiation protection guides.

The Task Force presented two options for public discussion, both of which would leave EPA in a lead role, while clarifying its relationships with other agencies. One option is to give EPA lead agency authority; the other is to establish an interagency radiation protection committee, chaired by EPA. Options are also presented on ways in which guidance might be developed in the future.

Finally, the paper on institutional arrangements discusses whether there is a need to reestablish a cabinet-level interagency council to coordinate the overall development of radiation policy. This entity would be modeled on the old Federal Radiation Council, which coordinated Federal radiation protection activities during the 1960's, but the scope of its activities would be broader. It would oversee both research and protection activities, as well as matters that do not fall squarely within either category.

The major arguments against establishment of a radiation coordinating committee are, (1) that it gives special treatment to a single environmental hazard at a time when many hazards compete for attention and (2) that it sets up another layer of decisionmaking and may therefore encumber rather than assist policy development. The alternative would be to set up mechanisms through which research and regulatory activities could be coordinated without the establishment of a formal council. Public comment on all of these alternatives has been solicited.

All that now remains is for the Task Force to review public comments and to make a final report to the White House. We hope to complete this task by early June.

I have tried to sketch the subjects examined by the Interagency Task Force and its Work Groups and to describe how the project was conducted. I will be pleased to answer any questions you have.

DISCUSSION

MR. KASTNER: I am not sure this is a question as much as a comment. In talking about low-level effects from ionizing radiation, I am not sure that the Utah or the Smoky situation is that kind of thing. There is sort of confusion that gets caught up in the public mind when you talked about low-level effects of radiation, assuming that that is something under 5 rem a year, when clearly this is not a case of the relationship between cancer and the low-level effect being uncertain so much as the dosimetry being so uncertain, and certainly higher than 5.

MS. BLACKBURN: I agree; that has been a problem. In fact, it was a problem for us, or for the staff anyway working through the Task Force process. All I can say is that studies are underway to remove uncertainties that exist with the available dosimetry data.

MR. KASTNER: In this respect, we keep pounding away at the fact that this is not an effect of low-level radiation; that we are talking about a higher radiation.

MR. KEMP: If they are not sure of the dosimeters, how can you be sure it is high?

MR. KASTNER: Possibly high. I just want to point out that we are talking here, not only about external radiation, but inhalation.

DR. SOLON: How will the implementation of this study prevent the quasi-obfuscation, or suppression of scientific reports, such as results of the Utah epidemiological studies and the Smoky results?

MS. BLACKBURN: I do not think anything in this report directly addresses your question; however, I refer you to the press statements issued by the Secretary in February and March of this year, stating his commitment to release everything that we have in our files. That release is ongoing. Over 20,000 pages have been released. To state again, he is commited to release studies as we become aware of them.

DR. SOLON: Maybe the report should address itself to the problem of kind of high-level executive decisions by decision makers to withhold, or obscure, or in some place attenuate information which should be addressed overall and collectively by the scientific and public health community.

MS. BLACKBURN: Hopefully, establishment of the entity we have described as analogous to the old FRC will help that; the radiation coordinating council. Also, there is a section in the public information report specifically directed to military and civilian personnel, to assure that they get information as soon as it becomes available on any tests applicable to that group.

MR. SHREVE: I wonder if you would repeat for me what I thought I heard. The subject is a registry of exposures of occupational workers. I understand it was recommended and then if I understood the tag line of the report of that committtee, they saw a need for it, but then they refused to recommend it as an action. I am particularly interested in connection with underground uranium miners. For years we have been urging this notoriously job-hopping group to try to be followed. We tried to do it among the companies in Ambrosia Lake at considerable effort of company personnel to pass cards around and we could do 3 months, or 9 months, and someone else would pick up and fill in, and we finally got a reasonable population together to do our own epidemiological study, supported by the industry, done by the University of New Mexico. So, did I hear correctly, that everybody thought there ought to be one, but they refused to recommend it?

MS. BLACKBURN: Three reports--reduction, records and privacy, and science--discussed a national worker registry. The science work group, in one of the appendices, spent 8 to 10 pages discussing this concept and recommended a feasibility study, rather than the immediate establishment of a registry. As I am sure you know, if you have had experience in this area, the establishment of a worker registry is complex. There are a lot of questions that remain on how such a registry should operate; whether it should be central; whether records should be kept by the Federal Government; whether they should be kept by the individual institutions; whether they should be kept on a State basis; and what kinds of information should be included. What the science work group recommended was a feasibility study to answer these questions.

MR. SHREVE: So the recommendation is to put off the decision; thank you.

MR. BLACKBURN: It is to get more information so that we can make a better informed decision.

MR. ADAMS: I am inquiring about education. Yesterday, Dr. Hilberry said the public cannot be educated with respect to radiation; this morning Dr. Brodsky said they can. It seems to me that it is mandatory that they be educated. I do not believe we are going to see the end of the emotional response of our poeple until substantial groups of them do understand something about radiation--the risks that are involved--and can make the social decisions on the process we are trying to use. I was interested your interagency group appears to have considered funding research in protection activities; I did not hear you say anything about providing anything for education of the people, which in some ways of looking at it is our most critical problem.

MS. BLACKBURN: I could not agree with you more. In fact, the 50 some odd pages of the public information report address exactly the question you have raised. We have proposed educational programs directed, not only at the general public, but at three target groups. In addition, the Public Information report has proposed establishment of an advisory council to get the vocabulary together to make understandable messages.

DEVELOPMENT of RADIATION PROTECTION GUIDANCE for OCCUPATIONAL EXPOSURES

Luis F. Garcia
Project Leader for Occupational
Radiation Protection Guidance
Office of Radiation Programs
U.S. Environmental Protection Agency

In this rather brief presentation, I shall attempt to give you as complete an overview as possible of the methodological approach being taken by the Environmental Protection Agency in its review and updating of the Federal radiation protection guidance for occupational exposures.

The current guidance is that developed by the former Federal Radiation Council and approved by President Eisenhower in May 1960, 19 years ago. It is emphasized here that this guidance is for the Federal agencies in the conduct of their occupational radiation protection reponsibilities. As such, the new guidance will impact at the user level only after it is translated into the standards and regulations of the regulatory agencies.

The principal activities involved in developing the new guidance are indicated in Figure 1. First of all, I would like to direct your attention to the numerous outside inputs to the process. The sources of those inputs constitute the radiation-protection milieu in which the process takes place. The development of the updated guidance thus involves taking into consideration the numerous relevant changes which have taken place in that national and international milieu over the past 19 years. Those changes are not confined to those arising from the increased knowledge involved in estimating the risks. They also include the increased and different occasions for occupational exposures, as well as attitudinal changes toward occupational risks.

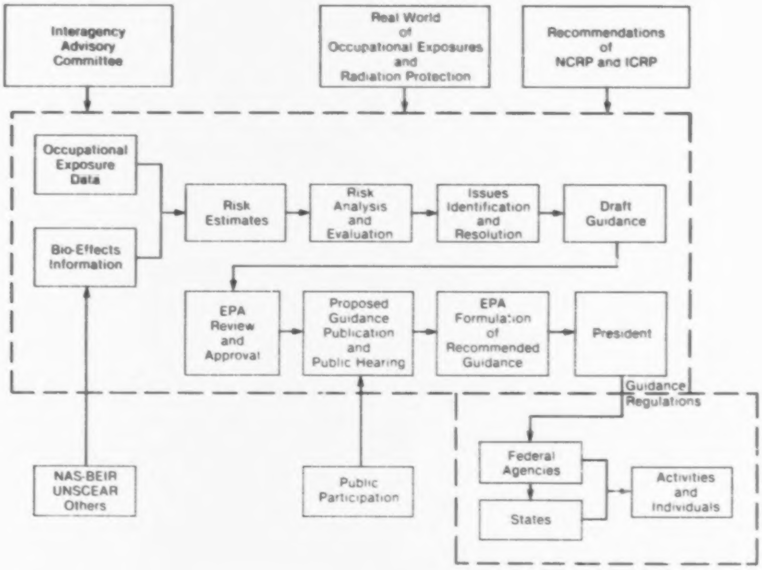
Interagency Advisory Committee
Real World of Occupational Exposures and Radiation Protection
Recommendations of NCRP and ICRP
Occupational Exposure Data
Bio-Effects Information
Risk Estimates
Risk Analysis and Evaluation
Issues Identification and Resolution
Draft Guidance
EPA Review and Approval
Proposed Guidance Publication and Public Hearing
EPA Formulation of Recommended Guidance
President
Guidance
Regulations
Federal Agencies
States
Activities and Individuals
NAS-BEIR UNSCEAR Others
Public Participation

Figure 1. Development of new radiation-protection guidance for occupational exposures.

In spite of the many advances which have occurred, establishing the numerical values for the Radiation Protection Guides still requires the application of judgment. In other words, there is no calculus for determining those values mathematically.

For the purpose of the new guidance, an occupational dose is one received by an individual during the course of gainful employment activities (either as employee or self-employed person) from exposure to sources other than those from normal background and from purposeful medical exposure as a patient. As such, the guidance is to apply to all occupational exposures without exception and will be structured accordingly. Neither the term "radiation worker," nor any other artificially contrived one, will be used to label the worker who is actually or potentially exposed.

The first three activities shown in Figure 1--(1) Occupational Exposure Data; (2) Bio-Effects Information; and (3) Risk Estimates--have been essentially completed, except for having to take into consideration the findings in the forthcoming BEIR III report from the National Academy of Sciences. The next step is that of risk analysis and evaluation, followed by identification and resolution of principal issues. Formulation of draft proposed guidance takes place next, along with completion of its technical support document, which includes an economic impact analysis. After EPA review and approval, the proposed guidance will be published in the FEDERAL REGISTER inviting public comment. A public hearing will also be held, to afford a more ample opportunity for public particpation.

Final guidance is formulated taking into consideration the public comments received. The Administrator recommends to the President that he approve this new guidance to supersede the current one. Upon presidential approval, the Federal agencies will translate the contents of the new guidance into their rules and regulations.

Let us now take a look at some of the tentative findings of this guidance development process:

OCCUPATIONAL EXPOSURE DATA

Statistics on national occupational exposures have been obtained by EPA on the basis of 1975 data, and they will be published in a forthcoming report. Principal statistics derived from this study are:

1. The estimated size of the occupationally exposed work force is 1.5 million.

2. The compositon of this work force, according to major occupational categories, is shown in Figure 1. As indicated here, about 56 percent of this population is in the medical field; and only about 6 percent in the nuclear fuel cycle.

3. The contributions of these occupational categories to the national collective dose (i.e., person rems) are shown in the bottom part of Figure 2. Medicine contributes about 44 percent of this collective dose; and the nuclear fuel cycle about 18 percent.

4. Of primary importance is the distribution of annual doses in the national work force. As shown in Figure 3, nearly 66 percent received a "less than measurable" dose; 95 percent less than 0.5 rem; and only 0.2 percent greater than 5 rems. The dose distribution in the component sectors of the work force does not differ too significantly from this one. Such distributions are used to judge, partly (not wholly), the significance of the need for exposures above (or between) the levels of interest. The "need for exposures" is an important factor in the decision matrix used to select the numerical value of a Radiation Protection Guide.

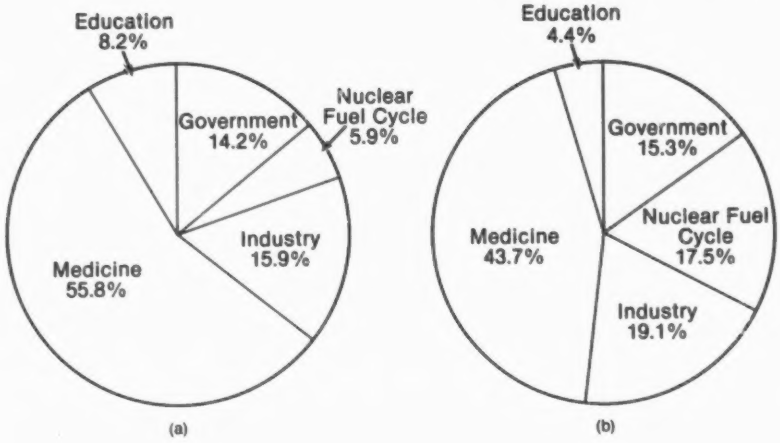

Figure 2. (a) distribution of workers by major occupational group and (b) distribution of collective dose by major occupational group.

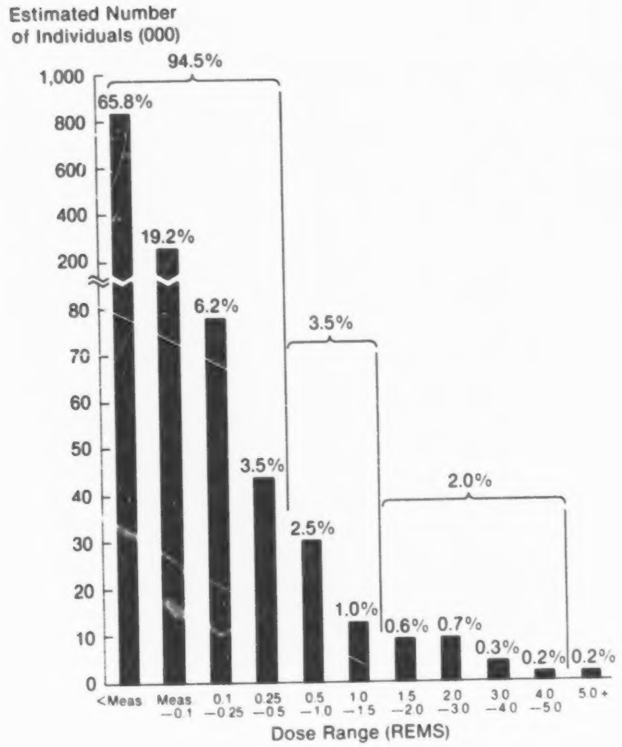

Figure 3. Estimated distribution of occupational doses.

5. As shown in Figure 4, the average annual dose was 0.11 rem to all workers; 0.34 rem to all measureably exposed workers and 0.85 rem to those in the maximum category (measurably exposed industrial radiographers). The average dose for measureably exposed workers in the nuclear fuel cycle was 0.63 rem; and 0.76 rem for those in the nuclear power plants.

	All workers	Measurably exposed workers
USA work force	0.11	0.34
Industrial radiographers	0.35	0.85
Nuclear fuel cycle	0.34	0.63
Nuclear power plants	0.39	0.76

Figure 4. Average doses (rems) in 1975.

BIOEFFECTS INFORMATION

It has proven useful to adopt the ICRP-26 classification of the deleterious radiation effects into the following two types: (a) Stochastic effects; i.e., those for which the probability of occurrence is a function of dose without threshold; and (b) nonstochastic effects; i.e., those for which the severity of the effect varies with the dose, there being assumed that for a given effect a medically objectionable threshold severity may exist. The risk-based objectives for selecting the numerical values for the recommended new guides can thus be stated as: (a) limiting the probability for the occurrence of stochastic effects to a level which would be considered acceptable; and (b) preventing the occurrence of nonstochastic effects of a medically objectionable severity. These objectives, however, do not lead to selection of unique values for the guides.

In the guidance development task, there is thus concern for the risks for the four distinct types of end effects:

1. Somatic effects:

   (a) Lethal cancer (stochastic);
   (b) Nonlethal cancer (stochastic);
   (c) Nonstochastic effects of a medically objectionable severity; and

2. Genetic effects (stochastic).

The risk models used to date in the guidance development task are the ones described in the BEIR Report; and the risk coefficients are those obtained from that report and others. The dose-effect information in the forthcoming BEIR III report will be taken into consideration in the formulation of the proposed new guidance.

RISK ESTIMATES

The complex nature of the dose-effect relationship models for lethal cancer made it necessary for EPA to search for appropriate means for determining and expressing the individual risk arising from repetitive annual doses during a working lifetime. This led to the [illegible]on of the life table model for this purpose, as described in a recent EPA report. This procedure provides the means for estimating the "lifetime" risk faced by an 18-year-old individual about to enter employment in which he will receive a given dose annually until age 65--the competing risks of death being taken into consideration.

[illegible]om the use of this methodology provide some useful insights. First, [illegible] of death, from whatever cause, is unity for everyone, it is better to [illegible] of concern here as a "premature death." Because of the latent [illegible]d other cancers, the life table methodology indicates that the average [illegible] life lost per premature death from occupational radiation exposures is [illegible]ding on the BEIR I model used. This statistic is independent of the [illegible]se within the range of interest. Use of the life table model for [illegible] to nonradiation risks of death from on-the-job accidents also gives [illegible]icates that the years of life lost per premature death is about 35 [illegible] that for radition-induced cancer deaths.

[illegible] can be used to estimate what is the equivalent annual risk of death [illegible]ts for a given annual dose--in terms of two end effects: (a) number [illegible] the cohort, and (b) number of years of life lost to the cohort as a [illegible]ure deaths. Let us look now at what the equivalent nonradiation [illegible] annual dose rates of interest.

[illegible] the equivalence in terms of the number of premature deaths for the [illegible] doses of interest--on the basis of the four BEIR I risk models. We [illegible] annual doses are "equivalent" to the average annual risks of death [illegible]ents in the low-risk occupations. The risks in the occupations [illegible]are *average* ones. Individuals in each of these occupations actually [illegible]s, the highest risk likely being several-fold higher than the indicated [illegible]rems/year represented an average value, instead of a maximum one, [illegible] exposed work force, its equivalent industrial risk would be 1 to [illegible] average one in the three highest-risk occupations.

[illegible]he equivalent risks of these same average doses of interest, but now [illegible]rs of life lost. For this case, the equivalent risk for a hypothetical [illegible]/year would be lower than the average risk in the three highest-risk [illegible]s.

[illegible]of reliable data on risks of death from occupational causes in the [illegible] the various nonradiation industries. Nevertheless, efforts are now [illegible]h data in order to provide a comparative perspective for maximum [illegible]r a given set of radiation protection guides.

[illegible]es the estimated risks of incurring a nonlethal radiation-induced [illegible]y the same as those for lethal cancer.

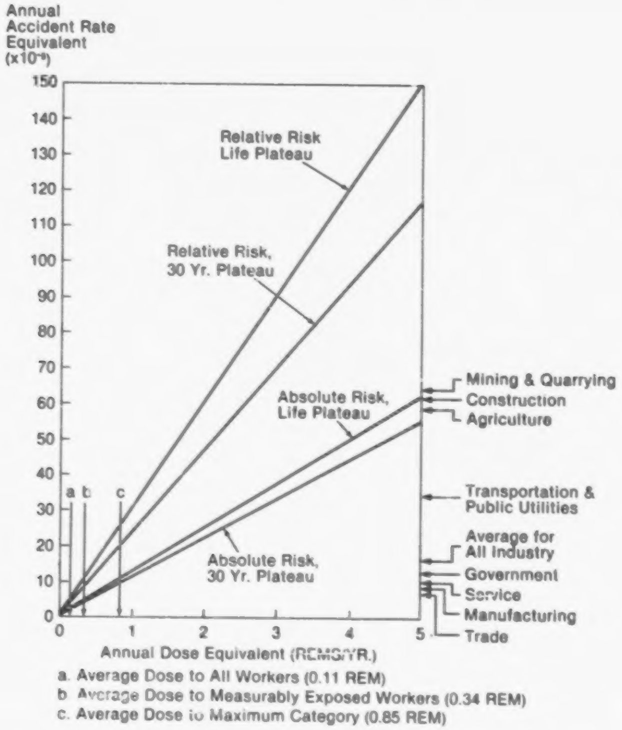

Figure 5. Annual accident rate equivalent in deaths by dose level and risk model (exposure interval: Ages 18-65).

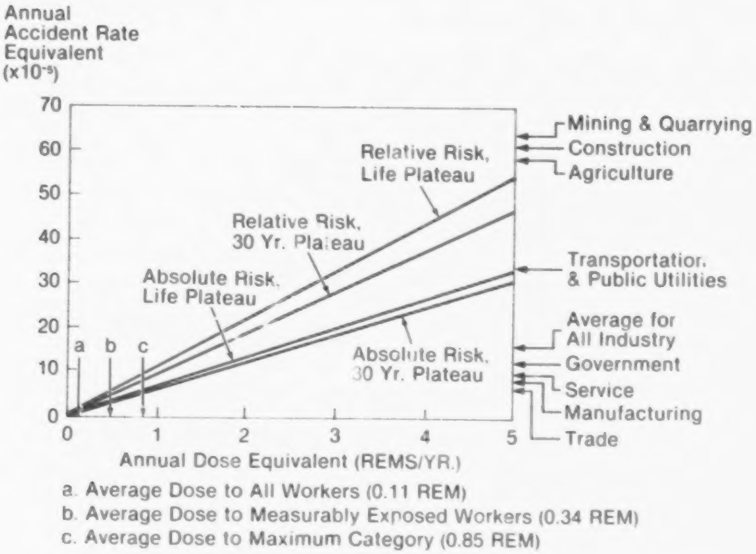

Figure 6. Annual accident rate equivalent in years of life lost by dose level and risk model (exposure interval: Ages 18-65).

Additionally, there are the genetic risks involved in the irradiation of the gonads. Estimates of the genetic risks for all progeny generations, as shown in Figure 7, are as follows for the average annual doses of interest:

All radiation workers (0.11 rem) - 0.02-0.4 percent
Maximum category (0.85 rem) - 0.06-1.4 percent
Maximum allowable (5.0 rem) - 0.4-8.4 percent

- Natural incidence is 6% (per liveborn)
- Average to all radiatin workers is 0.02-0.4% (all generations)
- Average to worst category of radiation worker 0.06-1.4% (all generations)
- These risks numerically comparable to lethal cancer risks

Figure 7. Genetic risk estimates.

This may be compared to the natural incidence of 6 percent per liveborn in the United States.

In evaluating current and proposed guidance, the risks of the three different types of stochastic effects are considered to be of an additive nature. Additionally, the occupational radiation risks must be viewed as incremental to the occupational nonradiation risks faced by the worker.

TENTATIVE FINDINGS AND CONCLUSIONS

Analyses and evaluations carried out to date lead to the following tentative findings and conclusions:

1. Average risks under 1960 guidance are low. On this basis alone, drastic revision of the guidance is not warranted.

2. The 1960 guidance is unnecessarily high for the 95 percent of the workers now receiving less than 10 percent of the average annual limit. The new guidance should be structured to provide an "effective" lower limit for that large segment of the work force, which contributes a significant fraction of the collective dose. Application of the ALARA principle to such a lower effective limit would serve to focus attention on reducing doses to truly ALARA levels and on eliminating many otherwise unnecessary exposures--thereby leading to a reduced collective dose.

3. As permitted under the current 5(N-18) guide, 12 rems in any 1 year does not appear to be justified. There is no apparent significant need for the dose in any 1 year to exceed 5 rems. The 5(N-18) guide should probably be abolished as a prospective guide.

4. There is an apparent decreasing need for doses in excess of 0.5 rem and up to 5 rems. Analyses are underway to determine the optimal value at which to set the Radiation Protection Guide within this range, in accordance with the following objectives:

   (a) The annual guide must be low enough so that the associated lifetime risk for maximum exposed individual is considered acceptable;

(b) The guide should be high enough to afford the degree of operational flexibility required in essential activities;

(c) The guide should not be lowered to a level that would result in an objectionable increase in the collective dose or in costs that would exceed the expected benefits.

5. It appears to be impossible to meet all of these objectives by guidance that contains only one single numerical guide, as at present, even though application of the ALARA principle is a required condition. One possible satisfactory solution, shown in Table 1, would consist of an annual RPG of 5 rems, broken down into 3 ranges (each starting from zero): Range A--0 to 0.5 rems; Range B--0 to 1.5 rems; and Range C--0 to 5 rems. Applications of the ALARA principle is a requirement for all 3 ranges; and the higher the range the more stringent the additional requirements become. The one weakness of this particular set is that the maximum feasible lifetime accumulated dose is the same as that of current guidance (i.e., 235 rems), whose lifetime risk appears to be unnecessarily high. Hence this particular guidance may have to include a specific restriction for limiting the lifetime dose to a fraction of the 235 rems. This introduces what some would view as burdensome administrative complexity. A possible solution to this issue would be the reduction of the annual RPG to a level that would obviate the need for a separate lifetime dose limit. Such a solution, however, would have to satisfy all three of the objectives stated above. Compromises will have to be made to satisfy all three optimally. Work is underway to determine such an optimal solution to this issue.

Table 1. Graded scale of radiation protection requirements.

Range*	Whole-body dose (rems) in any one year
A	1. Exposures justified and ALARA 2. Individual monitoring as required to assure exposures are within the the range and are ALARA. 3. Basic knowledge of radiation hazards and radiation protection principles, and of the radiation hazards specific to the job.
B	The above, plus: 1. Radiation protection supervision to assure exposures are justified and are ALARA. 2. Mandatory individual monitoring and annual recordkeeping. 3. Consent of fertile female workers.
C	All of the above, plus: 1. Prior justification of need and radiation protection supervision on a task basis to assure exposures are ALARA. 2. Individual monitoring on a task basis, and lifetime recording of doses in Range C. 3. Formal consideration of previous exposure and age.

*Range

A	0 - 0.5 (or 0.1RPG)
B	0 - 1.5 (or 0.3RPG)
C	0 - 5.0 (or 1.0RPG)

NRDC's POSITION on LOW-LEVEL RADIATION EXPOSURE

Arthur Tamplin, Ph.D.
National Resources Defense Council

The title that I was given was NRDC's position on low-level radiation. I will just briefly discuss that. NRDC has a petition before the Nuclear Regulatory Commission and the Environmental Protection Agency requesting a reduction in the occupational exposure limits. We feel that any standard which allows an individual to accumulate a dose of 60 rems by the time he is 30 years old, is just an inappropriately high standard.

The other aspect, when we consider occupational exposure, is that occupational exposure is not simply a problem for the worker to decide himself because of the genetically significant exposure which the worker obtains. The defective genes which will be created, will become admixed with the genetic pool of the population as a whole so therefore the exposure of the workers is also a societal problem and not one to be left totally to the workers. The same thing, of course, applies to the woman in child-bearing age who may be pregnant. The decision to expose that developing fetus certainly is not the sole prerogative of the mother, and the fetus should receive some consideration in that matter. On this basis then, the NRDC has petitioned for the lowering of the occupational exposure standard.

I noticed the comment from EPA as to why they were in occupational exposure. We initially petitioned the Nuclear Regulatory Commission to reduce the occupational exposure standard. We got a call from Bill Rowe of EPA, who was upset that we did not petition them too--clearly a jurisdictional problem. We did then petition EPA a month later, and quite quickly EPA rejected our petition. Subsequent to the publication of the Mancuso report we asked EPA to reconsider our petition and we understand it is now open again. The Nuclear Regulatory Commission kept our petition open (about 2-1/2 years now), and has now directed the staff to expeditiously conduct public hearings on the petition. The approach which we have seen that the NRC staff may be going to take toward our petition, is from a briefing which they gave the commissioners, it was that this whole thing can be handled through ALARA. Well one of the problems with ALARA is that it is unenforceable and in order to make ALARA enforceable, the NRC will have to generate some new regulations.

The other thing is that this ALARA is kind of a scapegoat and it takes me back to 1969 and 1970 when we were concerned about the exposure limit for the general public, which was 500 millirem. The comment from both the AEC at that time and the nuclear industry was, "well, we don't expose people to that much." You know the exposures we give the people is far below that, so we do not know what you are arguing about.

Our comment at that time was that if indeed you can expose people to much less than that, then you should put the regulation where your mouth is. Otherwise, you are saying a regulation is meaningless. At that time they were talking about ALAP as low as possible or practicable. That is another thing that confuses me about this whole area and I am sure there is some bureaucratic subtleness involved in it. So why in the hell was ALAP ever changed to ALARA? I cannot figure it out but somehow or another, I think I have been had, and that disturbs me, but someday maybe it will come out.

Anyway, the use of ALARA in terms of occupational exposure in saying well we are never going to expose anybody to that much anyhow, is the same old impractical argument that will be totally misunderstood by the public. The public as a whole could not understand why they did not lower the regulations if indeed it was possible for nuclear power plants to meet much more restrictive regulations. Of course the Atomic Energy Commission did subsequently in Appendix I, reduce the allowable releases for nuclear power plants in accordance with the kind of statements that the nuclear industry was making. I think we have to do the same thing with respect to occupational exposures. Not say, well we are going to handle it with ALARA, but put definitive numbers in there so that the public and the workers and everybody knows precisely what we are talking about. I heard yesterday that a lot of people think people in the radiation protection industry are wearing black hats--and this ALARA approach and everything is part of the reason. There is another reason, and that is in the 1972 BEIR Report (by the way our petition is based upon the 1972 BEIR Report), they gave two estimates of the biological effects for radiation; cancer induction. They also, without ever explaining it, gave what they call their best estimate.

Now the people in the radiation protection area and in the nuclear power industry always chose to use that middle estimate or in some cases even the lower estimate. The BEIR committee itself said they could not choose between the two; they did not know which was correct. One was based on the absolute-risk and the other on the relative-risk approach. The committee stated that they could not choose between the two. Now from a public health point of view, the upper limit is the one that should be employed, and generally I think the general public recognizes that. In other words, in ignorance, beware; be conservative and use the upper limit guide.

Another thing, in the 1972 report, the BEIR committee indicated that they did not know whether the linear hypothesis overestimated or underestimated the effects of low-dose radiation. It was stated explicitly in the report. Here again, the radiation protection people, the Nuclear Regulatory Commission, and environmental impact statements, the industry, all said that these were conservative estimates using the linear hypothesis. Now all you have to do in order to counteract that with the general public is read what the BEIR Report said. And the language in that respect was straightforward. The bureaucrats and the industrial Ph.D's were literally trying to kid the public. They were trying to lie to the public and it was a simple matter to refer to the BEIR Report to point out that error in judgment which the people who were supposedly representing the public were making. I do not know what the new BEIR Report is like. I have a feeling that I may have some disagreements with it. However, the new BEIR Report is coming out now in the presence of the studies of Mancuso and Bross, and these studies indicate that the biological effects of radiation may be worse than was estimated in the 1972 BEIR Report.

Now you couple with this the fact that both of these studies were removed from the investigators by a process which seemed less than honest, and I think this whole problem of what are the low-level effects of radiation and what meaning does the new BEIR report really have, is going to be in serious controversy because of it. The Libassi Report, semiaddressed the Mancuso and Bross stuff. Now we were told, and it is true, that during the early phases of the Libassi Report that people from public interest and environmental groups were brought in. I appeared at the meeting where the epidemiologist (I guess Heath) was discussing the Mancuso and Bross reports and specifically asked him if he was going to put forth a believable report, to address two tables--one in the Mancuso report and one in the Bross report--and if he was going to set those studies aside as having some relevance, then he should do it by setting aside those tables.

That was not done in the Libassi report. Instead they included in the Libassi report, a rather sophomoric paper by a Dr. Land. I use sophomoric, sort of a tongue-in-cheek because that paper could have been written by anybody who had completed Probability 1A. It is just not going to stand up as some kind of a refutation of the Mancuso and Bross studies. So this controversy is going to continue. Hopefully in the Nuclear Regulatory Commission hearings, we will be able to address these things in a public format and in an adjudicatory fashion where the fine knife of cross-examination will be able to bring forth the facts from the fiction. I do not anticipate that those hearings will resolve the issue but at least they will point out the true uncertainties that exist and also indicate that prudent public health practice suggests that if you are going to err, you err on the side of the public health. I think that will be a very interesting, educational process for the public. I think, unless this whole subject of Mancuso and Bross is addressed appropriately, unless the people involved in this regulatory process really discuss the uncertainties and do not pick a lower number that makes everything look good, that the nuclear bureaucrats are going to continue to be people wearing black hats.

Another failing of the Libassi report, and as I read the memorandum of Brszynski at the time that that memorandum was prepared, there was serious concern about people; the soldiers who were exposed during the testing at Nevada, and the civilians who were exposed in Nevada and southwest Utah. Before the Libassi Report was made semi-public, there was an article published in the New England Journal of Medicine by a Dr. Lamb, if I remember the name correctly, that indicated there was a significant doubling of the leukemia incidence in the southwest Utah area. The Libassi report did not address this at all, it did not address the exposures of the workers, it did not seem to me that it even suggested anything except some additional studies that should have to be performed over the next 20 or 30 years. The situation is, that there are existing problems with existing people that have to be resolved and they cannot wait for a long-term epidemiological study to be conducted. They have to be resolved on the basis of the information available today. The Libassi report simply cites that issue.

This is one of the reasons why this whole thing is becoming so politicized. You cannot get the bureaucracies to do anything. You submit a petition to them and they have to conduct a 2- or 3-year study in order to understand whether they should do anything about the petition. You wonder what the hell they have been doing for the last 10 years if they have to now go out and conduct a 2- or 3-year study. It seems to me that the issue is going to probably be taken out of the hands of the nuclear bureaucrats. It may be resolved politically because there are a lot of congressmen who are running around now holding hearings on the issue. That does not mean they are going to do anything about it, but at least they are increasing the public awareness.

The other thing that is happening is that these things will be going to court. So far as workers' exposures goes, there has already been 3 cases settled in England associated with exposure at Windscale. Individuals received dosages from 50, 27, and I think 47 rem, and they died of cancers. In the case of the 50 rem exposures, they were given the maximum allowable compensation under English law, in the case of the 27 rem, they were given 1/2. This is sort of a sliding scale on the linear-dose response relationship. There was also a case settled out of court, in Idaho, of a worker who was exposed. My impression of the exposure which he got was something like 30 rem.

At the present time, there are 400 files or claims against the Government associated with the individuals in southwest Utah. As I understand it, that number is growing every day. And of course the soldiers' issues will have to be resolved through some kind of a situation within the Veterans Administration, or probably politically. Maybe the courts probably could not handle all the claims that are coming up associated with southwest Utah. So there may have to be some political resolution of that. This issue I am sure will win in the courts with a jury of 12 uneducatable people. The only thing that I would say is that it is time, as I heard yesterday, for you to be honest. If you are going to go out there and educate the public, if Libassi is going to get this public information disemination group going within HEW, then you had better do it right, because I do not know whether anybody would believe a pamphlet that came out of HEW today. Certainly, if the first one that comes out does not tell the whole truth, then I think HEW will be in as serious trouble as the old AEC was.

DISCUSSION

DR. SHLEIEN: I really do not have any question, I have an impression, and Dr. Tamplin, I do not have to preface my remarks by saying that I respect what you are doing in terms I think that individuals that are the naysayers are important to society. It is also important to realize that just as there is as you say, a nuclear bureaucracy, and governmental bureaucracy, there is also an anti-establishment, environmental bureaucracy just as well established as the other. My own feeling, sitting here, was that there was some feeling and perhaps I felt it a little too strongly, that there was some guilt by association, and I do not like that technique. I do not like to feel that because I am associated with a Government bureau and because I have invested 20 years of my life in this kind of work, that somehow I am not capable or not honest enough to protect the health of this nation. I claim that I am just as honest as people in the anti-establishment.

DR. TAMPLIN: I do not know what is meant by establishment; I think bureaucracy is a fairly well-defined word. Personally, I think there are good people in bureaucracies, but bureacracies are also a sociological phenomena, and bastards and cream both rise to the top. I am not anti-establishment, I used to be with the establishment. I spent a lot of time in the establishment, I know there are some good people within the establishment; but I also know what the establishment is capable of. One of the major reasons why I participate outside of the bureaucracies today is that the good people within the bureaucracies need a constituency. Without a constituency outside the bureaucracy, the competent people within the bureaucracy will not be able to perform their job the way they should. I am not anti-establishment. I talked to Philip Stern and he said, why do we need bureaucracy and I just said, well I do not know how we could get along without it. What we do need is to create a constituency outside the population to support the good people who are in bureaucracies. We cannot continue to suffer under Liverman. There are other people within DOE who are more competent and more honest than Liverman and so from my own point of view, that is what I am doing. If you are one of the honest, straightforward people within the bureaucracy then I am working for you, because if you ever get into trouble with the bureaucracy, you will have a constituency on the outside to protect you.

DR. SOLON: This question is for Ms. Blackburn, and it is not a scientific or public health question, but a legal question. In the last 2 weeks, the New York Times editorially suggested, that a deficiency or failure on the part of either industry, or Government, or public health officials, or whomever has information, to withold it should be answerable. The failure to disclose or reveal or completely, candidly answer questions in the scientific and public health area, should be made answerable before a magistrate in a court as, presumably, a felony. Specifically, they were addressing the Hooker Chemical Company's failure to disclose the emptying of certain kinds of caustic materials into the environment in the neighborhood of the Buffalo area. I wonder, if in terms of the interagency studying that you legally address, how the general thrust or sentiment would be toward that kind of answerability for failure to make complete and full disclosure of public health issue in the scientific area; the radiological area.

MS. BLACKBURN: Our study did not address that question, but as you know, there are two pending cases, Con Ed versus the U.S. et al., in eastern Pennsylvania, and the Jaffe Case, which touch upon the question raised; whether there is a duty of the Government to issue a warning. Because I am involved in that litigation, I do not think I can comment. We did not address the issue that you are raising now in the Task Force. We did not see that as the mission of the Task Force to try and decide what to do in the event of a coverup.

DR. SOLON: As a guy that works in public health, I feel that there is a certain obligation upon me in terms of my constituency to say what I know, when I know it, and I feel that there should be this kind of constraint generally. Insofar as your interagency task force did not address this problem of accountability, I think there should be this accountability and, yes, I would like to make it part of the sphere of focus of your task force.

MS. BLACKBURN: I will carry your message back.

MS. BLACKBURN: I will carry your message back.

DR. AUGUSTINE: In my trying to fill in for Dr. Hilberg this morning, I did not specifically mention that the BEIR committee had considered what they consider all the available evidence available today, including the Mancuso study of the Hanford workers, the study of the Portsmouth Naval shipyard workers, and the other studies that have been in the press for the past few years and the BEIR committee did not find anything in those studies that would support changing their risk estimates.

DR. BRODSKY: There are a number of things I would like to discuss with Dr. Tamplin. I will try to keep it as brief as possible. I believe you may remember that I appeared with you at the 510 CFR 50 ALAP hearings in favor of lowering the environmental limits for reactors. I personally feel it is possible to stay less than 20 rem for a lifetime exposure. I think that the climate of consideration with the NRDC report, as I have seen it, and I have been working in a group where I have been able to observe Bob Alexander and other people considering this NRDC petition, has been a very fair one, a very honest one. From what you have heard the EPA say today and from what I hear being discussed within NRC, I think the NRC will probably address a number of the issues raised in the NRDC report, which are good issues, and there will be probably some lowering of some standards in some way. But there have also been discussed in some of the NRC documents some reasons why the NRC may not be able to adopt in toto and verbatim what the NRDC wishes. I do not think this is cause for saying that all bureaucrats who do not adopt every word that the NRDC says are dishonest, and the only ones within the agency who are honest are those who would eventually agree with the NRDC. First of all I have been in this field for 30 years. I think I am as honest as anybody else and I think I can show many, many, documents to prove that I have fought within and outside the agency for lowering of limits where I thought it was appropriate, and for imposition of thousands and thousands of dollars of expense on industry where I thought it was appropriate. Dr. Tamplin asserts that the Mancuso and Bross studies have validly indicated at least that our estimates and the BEIR estimates on the absolute-risk basis may be too low. There is a Dr. Terence Anderson who has published in Health Physics (all of you can read it), a journal which is also fair enough to publish Mancuso's results, part of Sander's results, a paper of mine which is going to be published. I think it is a fair journal; they did not exclude Mancuso; they published several articles from Kneale and Stewart. But I think if you want the total picture, you can look at Terence Andersons's article, you can look at Gilbert's publications; you do not even have to mention Jim Liverman. You can go back to Ken Rothman. Dr. Rothman is an associate professor at Harvard; I think it is a reputable school that you have all heard of. Rothman, in his talk, not only invalidated Bross' claims, but he went to the trouble of addressing the Mancuso report and invalidated it as well. I worked with Dr. Mancuso as co-investigator for 8 years. I can show you a file cabinet full of reasons why his presentation is absurd. Yet we think of it as scientific truth today. Why? Because the T.V. cameras turn on when Mancuso speaks and when Tamplin speaks--they turn off when all the rest of us speak. There are other references in the paper that I will publish as part of these proceedings and you can read them. Anybody who wants a simple explanation of why the Mancuso and the Bross papers were not only sophomoric, they are not even worth a high school paper in some instances--I will be glad to talk to any of you about why. I have given these in detail before the House Subcommittee on Health and the Environment, but the newspapers do not read that. I have shown at least 2 dozen idiocies, completely incompetent attempts at analysis of data. I just went through about 1/3 of the Mancuso report, and I could have given a hundred, and yet this paper is being propagated as scientific believability. Well I guess I have said enough to get the point across.

DR. TAMPLIN: I thought I was very careful when I spoke to say bureacracy and not bureaucrats and clearly the remarks of which I made here today were not directed at any one individual, except I guess I did single out Liverman for special praise. I might say one thing about the Mancuso report, and I am not here to debate the validity of it, but there was one table in the report and I can't remember now whether it was table 11 or 12. When the NRC staff itself prepared an evaluation of the Mancuso study, which they sent up to the commission, and they indicated that subject to some caveats, the Mancuso report suggests that their previous estimates of the biological effects of radiation may have been too low, one of the major arguments or basis for that particular statement was this particular table. I do not know whether Dr. Brodsky has subsequently looked at that table, but in the material which I saw that he submitted, he did not look at that particular table. Now maybe you have at this time. This is not the place to resolve that, I just wanted you to know that so far as I am concerned and many other people, including Dr. Stewart and Kneale, that issue is not resolved, and it will come up again and probably, and hopefully, in the hearings which NRC is going to hold. I might say just one thing as I am somewhat pleasantly surprised with NRC. I think NRC is a much better agency than the old Atomic Energy Commission was. As I say, EPA dismissed our petition out of hand after having asked for it and NRC kept it on the docket and NRC has indicated they will hold hearings and our petition will be part of those hearings.

I do think that there are good people in bureaucracies and I think NRC is turning into one of the better bureaucracies.

REGULATIONS IMPACT on RADIOLOGY

Otha W. Linton, M.S.J.
Director of Government Relations
American College of Radiology

This marks the third year in which the American College of Radiology has been privileged to participate in your program. Those fine men and women who pay my salary have directed me to express their appreciation for the spirit of interest and cooperation which has motivated these exchanges.

If we ignore for a moment the big-brotherly posture of the Federal agencies, you, your radiologists, and their medical colleagues are symbiotic. Medical radiation uses are the staple of your programs. Without you, the radiologists would be unregulated, a heady state alien to nature in our times. Indeed, I have coined Linton's second law to express it more succinctly that "nothing unregulated is likely to stay that way." All of which makes you a sort of deux ex machina, a wave, a ripple, a splash, or perhaps a puddle of the shape of things to come.

As a matter of historic record, I must note that the College supported the 1959 Atomic Energy Act amendments and then cooperated with the Council of State Governments in fashioning the regulatory fetters you have clasped around us ever since. That was just 2 or 3 years after College members had lobbied the Federal Government to establish what is now the Bureau of Radiological Health.

You may attribute our motives to innocence, ignorance, or cunning gone wrong. I suggest that at least in part it represented a posture of professionalism and good citizenship. As a voluntary organization, the College sets standards, makes recommendations, and exhorts the faithful to good works. It lacks enforcement powers. It does not lack public responsibility.

In any event, 20 years later, you are such a familiar part of the radiation world that it seldom occurs to most of us to question the rightness of this or the certainty that you are here to stay. Indeed, given the Washington mania for improving health care, we wonder more about the future of radiology and the rest of medicine.

But now I must call to your attention that there is a cloud in your blue heaven. The porridge has a lump in it. The grand glories to come may be tarnished with crass coin of inflation. And that, I submit, poses a more immediate threat to you than it does to us.

To put it another way, you and all of your colleagues in the regulatory business have become expensive company to keep. That expense is not limited to your notorious salaries and excessive expense accounts. Out of politeness, we will mention these matters no further.

Instead, the major thrust of expenses are found in the costs of compliance with the whole gamut of regulatory activities. We may well be on our way to the greatest blowup since the Whiskey Rebellion signaled the Feds to stay out of home manufacture of honest corn.

Let's roll around some of the fun numbers.

Senator Hatch of Utah says Federal regulations cost each American family $2000 a year.

Secretary Kreps of the Department of Commerce estimates that complying with Federal regulations costs American industry $143 billion a year.

The Center for the Study of American Business estimates a more modest $79 billion tab for the private sector, whatever that is.

The Commission on Federal Paperwork estimated that paperwork costs industry up to $32 billion.

The Exxon Company claims responding to Federal regulations costs it $80 million a year and gives employment to 1100 persons.

None of that is us, you say correctly; or is it? If the Occupational Safety and Health Administration gets around to radiation workers, where does that leave you? Which side are you on when Secretary Califano tells every adult to get a chest x-ray to detect asbestosis, which cannot be treated in any event?

A bit closer to home, let us smack our lips over the New York Hospital Association's claim that two bits of every hospital dollar is spent responding to regulations. You do not have to believe all of that to relish the blatant absurdity. It amounts to $1 billion a year--to $60 a hospital day in some areas, like New York, and $41 a day if laid against the national average. Like some of you, I remember eating for $40 a month.

A couple of years earlier, the Ohio Hospital Association published 14 pages of fine print to list the public and private agencies to which a hospital and various of its personnel are accountable. You are on that list, of course, along with planning agencies, wage and hour inspectors, fire marshals, boiler inspectors, insurance inspectors, welfare inspectors, elevator inspectors; do I hear chicken inspectors? There too, lurk the alphabetical soup gang, the OSHA, the NRC, the FCC, the EPA, the HCFA, and onward till you bite your tongue.

Recently, the Maryland Hospital Association filed suit against I am not quite sure just whom, alleging that too much is enough, already. Maryland's hospitals are beset by 108 different State and Federal agencies, some of them contradicting each other in their requirements. The subject of the suit would add $3 million to the costs of billing Medicaid patients, for which they do not get paid very much or very soon anyhow, the Hospital Association claims. Besides, the State already has the information for its rate setting commission. The rate setting commission's estimate is that compliance with regulations, completion of forms, and busywork of committees costs the State's hospitals $19 million, or close to a third of a million a year for each hospital.

They cited the State requirement that hot water must be 110 °F or warmer and the Federal requirement that hot water cannot exceed 110 °F in patient rooms. Twelve different bodies regulate waste disposal. One State agency requires a steaming process and a second one prohibits the steaming process.

I recall the hospital in another State some years ago which was required to build a separate holding tank to trap liquid radioactive wastes. The city's sewage department then closed it off because of a prohibition on septic tanks for which it made no exception in this case, either. I learned several new words from that hospital administrator but I will not repeat them here.

But, is inspection bad? Is the purpose of regulations bad? Would not a hospital want adequate fire protection, even if the inspector did not come? Certainly. The insurance coverage depends upon it, among other selfish motives. Would it not want sanitary conditions in the cafeteria, even without the food inspector? Certainly, so that salmonella will not replace the common cold. And would not a good hospital want a safe radiology department, even without your periodic goading? Again, the answer is certainly. Most demonstrate it by hiring their own physicists to do more inspecting than you can do. But then, some do not do anything between your visits.

If we are to have regulations and if we are to be monitored, recorded and inspected to enforce those regulations, what are we getting for our troubles? This is where a danger lurks for you. Suppose somebody asks what you do all day? Suppose they then get really nasty and ask what you accomplished by all of those efforts? How do you answer? How does anyone answer? Or do you just quote W.S. Gilbert that "a policeman's lot is not a happy one."

Last summer, I sat waiting our turn while John Villforth and his boss Donald Kennedy were taken to task by a couple of old pros, Representative Paul Rogers and Representative Tim Lee Carter of the House Commerce Committee. Their purpose was to establish the level of ineptness with which the Food and Drug Administration was failing to measure up to the noble intentions and soaring rhetoric of Public Law 90-602, the 1968 Radiation Safety Act. Most of John Villforth's scars have healed by now. Some of it was a bum rap. There are many things that the Bureau of Radiological Health does splendidly. Indeed, I had thought the equipment performance regulations was one of them. But Congressman Rogers was not so sure.

He even brought out the information that BRH inspects very few x-ray facilities and depends upon you all to do most inspections. Sometimes, you do not do them very promptly. Sometimes, you do not do them very thoroughly. Sometimes, you seem to do them too thoroughly. Some units may not be inspected for a year or two after they have been put into operation. Some of them turn out to be just fine. BRH says nearly 30 percent have some flaw, either in installation or in reporting. What is a flaw? When is a flaw. When you say it is. That's when. Even if I have already had my own physicists check the thing out and correct any problems, its what you say that counts.

The New York Hospital Association report says that 16 percent of radiology costs and 22 percent of nuclear medicine costs can be laid against compliance with regulations of Federal and State agencies. With small variations, those figures did not differ significantly with size of hospital, type of hospital, or part of the State.

Those from New York City remember when Mayor Lindsey decided that all licensing programs would be self-sufficient. If the regulatory process is worth the time and effort that should have caused no difficulties. But somehow it did. As I remember, the budget was divided by the number of x-ray tubes in the city to get a per tube cost. For some of the larger hospitals with many units this came to more than $30,000 a year. For one office, the inspection fee jumped from $25 to $900. The City hospitals were exempted. The City should not charge itself. Then the voluntaries protested and were exempted. Only the proprietaries and the private offices remained. Then the thing went to court. The fees were paid under protest. At the moment, the City has lost twice but is refusing to pay back the protested fees.

You may say that's only part of the story. Undoubtedly, that is true. My point in citing the incident is to point to a revolt, apparently successful, against a regulatory program. In this instance, the revolt was against paying for the actual regulatory process, a relatively small part of the cost of compliance.

Last winter, Tom Shope and Harvey Rudolph circulated a third draft of their effort to assess the costs and benefits of the performance standards promulgated by BRH in 1974. Congress decreed that there would be performance standards. BRH had to figure out which ones. Theirs is a difficult task and I have complimented them upon the candor and integrity of their approach. Yet, they must start out by recognizing that there are no studies to indicate the impact of the standards upon radiation reduction, if any. Five years later, only 20 percent of medical equipment meets the standard. And it is arbitrary to assign a dollar value to estimated dose reductions to make a cost-benefit equation. A couple of years ago, the BEIR Committee of the National Academy of Sciences told the EPA that cost-benefit analytic methods are not very usable for radiation effects. Yet, the effort must be made in the current climate of accountability.

The BRH last month announced intentions to cancel its proposed ban upon the resale and refurbishment of used x-ray equipment not in compliance with the performance standard. The decision was based upon other cost-benefit analyses.

Another Federal health program, the Office of Professional Standards Review, has had to scurry around and devise analyses to prove that they are saving more on health care than the program costs. Their first analysis did not show a savings. So they quickly did another which came out better.

Where is all of this leading? I can only predict that things will get tougher all over. Low-level radiation is a hot topic, producing much more heat than light in most of the discussions. Occupational exposures to all kinds of toxic substances have become an equally hot topic. Suppose someone said that medical radiation is really quite safe as those things go. Perhaps we should divert our time, energy , and public funds elsewhere.

How would you handle that unlikely situation? Would we miss you? Would you take credit for making it safe? Would you argue that it is unsafe and find a bumper crop of violations to prove your point? Some of you, who can remain nameless, would do a little of this, a bit of that, and announce that safety is the product of eternal vigilance. Those are the ones who keep their budgets.

If the troops are restless, if they identify you as part of the inflationary process, if they rank you somewhere between a toothache and athlete's foot in the scale of social value, if they say they would not miss you if you went away, quietly please, what is to be done? Here is my only bit of advice. Try to be more helpful in solving the problems you cite. Your programs seek to avoid unsafe, bad practice. Try to make them enhance safe, efficacious practice. Somehow, get the chips off of your shoulders and off of the shoulders of your radiologists.

Just now, most of us are getting fired up about quality assurance. The College, the Bureau of Radiological Health, the manufacturers all have programs going. They involve techniques. They also involve motivations and not of the big-brother-is-watching variety. Come aboard with this. You see x-ray offices unknown to the rest of us. You should know who needs help. Help them, or try to pass the word about where they can get help.

Except with the really bad guys, you are not unwelcome, unless you make yourselves unwelcome, with radiologists and other physicians. Just as we are trying to do here, reach out a little. The stretch will do us all good.

CONTROL REGULATIONS are NECESSARY and EFFECTIVE

Marshall W. Parrott and Darrell L. Hocken
Radiation Control Section
Oregon Department of Human Resources

nglish language which, when used in conjunction with our city, State, nt, becomes the epitome of disdain. That word is "they." We tend to and regulation in terms of what "they" did. "They" just passed a les our practice--"they" are eroding our freedoms, strangling free islation--"they" won't let me practice without bureaucratic interferhey," anyhow? Some sort of alien beings who have taken over in this outlaw band of renegades dedicated to our destruction--some nefariwho have taken control of our lands and lives? "They" are none of the words of Pogo, we have met the enemy and "they" is "us." All of the re in the world are responsible for the laws and rules in force today.

t if this land were regulation free. Would this impact on you at all? reedom of choice? Could you operate decisively, effectively, without

y. There would be no laws covering collimation, filtration, chine function so we wouldn't need health physicists. There would be diagnosis of films by a radiologist to assure quality of diagnosis for o specialty courses for radiologists, or even further, the prerequisite n from an approved medical college. Remember, these would not be ulation free.

stand each other, let's see what regulations do achieve and why they they are effective.

ptable dose limit for a worker in the field of radiology was 200 During this same era, it was noted that the death rate among cantly higher than for other physicians. "They" passed a regulation osures to radiologists--making measurements to assure "compliance." ath rate among radiologists declined to a rate equal to or less than s. The "they" was "us." You asked for it--you got it.

atients? Should they receive a high radiation dose instead of the ecessary to confirm a diagnosis which would be life saving, otherwise regulation has not been imposed, nor hopefully will it, is whether the or not. This is up to the discretion of the physician in charge. How been asked to do a whole-body scan and asked only yourself why?

he Conference of Radiation Control Program Directors have heard ogists indicating as many as 80 percent of the x rays taken in nnecessary. It is intuitively obvious from the increase in malpractice ber of suits filed, why these films were taken, hardly for the purposes se or injury.

area at present is impractical, but certainly warranted--not for the otection of the physician from unscrupulous attorneys who fall in with ake a quick buck from your insurance. Here is an unregulated area could be effective. Not by us, "they" should do it!

Let us review the impact of x rays on a population in a small State in the Northwest. The information I have to present comes from Oregon only.

Figure 1 gives a view of the impact of regulations requiring filtration with accompanying inspection. For those unfamiliar with the requirement, filtration is added to reduce the soft, easily-absorbed x rays that create most of the biological effects while permitting the passage of the more energetic rays to produce an image on the film. An automatic patient dose reduction is accomplished. Collimation is another common requirement of radiation regulations (Fig. 2). Unfortunately, besides the mechanical aspects of a variable collimator as opposed to fixed device used at a variety of distances, it requires some operator skills. It is obvious that one can only regulate up to a point. After that, training and self-motivation become the key factors. I feel this figure shows the results of training and self-motivation among the various groups studied. The most discouraging statistics gathered come from the number of patients radiographed (Table 1). The only consolation is the increased care taken in the production of those radiographs because of the apparent shift from the non-radiologist private practitioner's office where collimation and other factors are not performed with the same skills and motivation seen in hospitals. The next trend, albeit without adequate statistics, appears to be a reduction in the number of patients exposed.

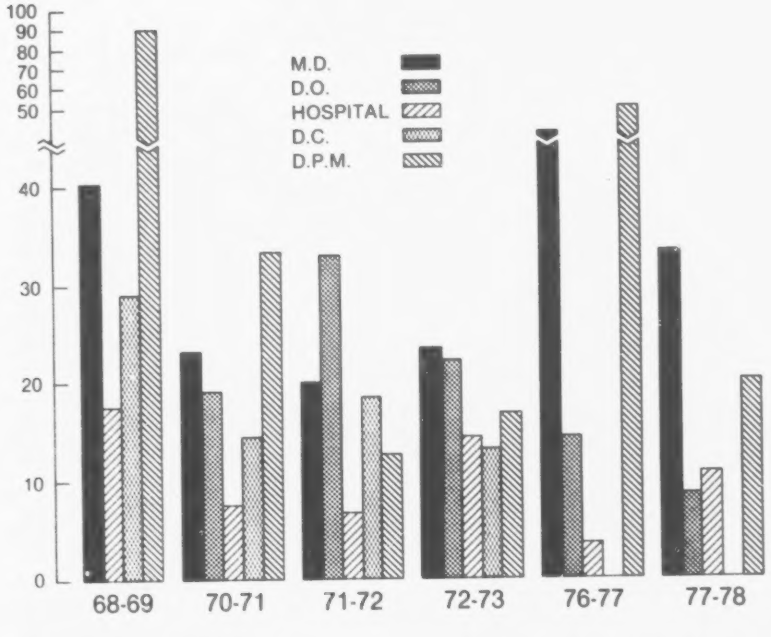

Figure 1. Percent of noncompliances for collimation by type of facility

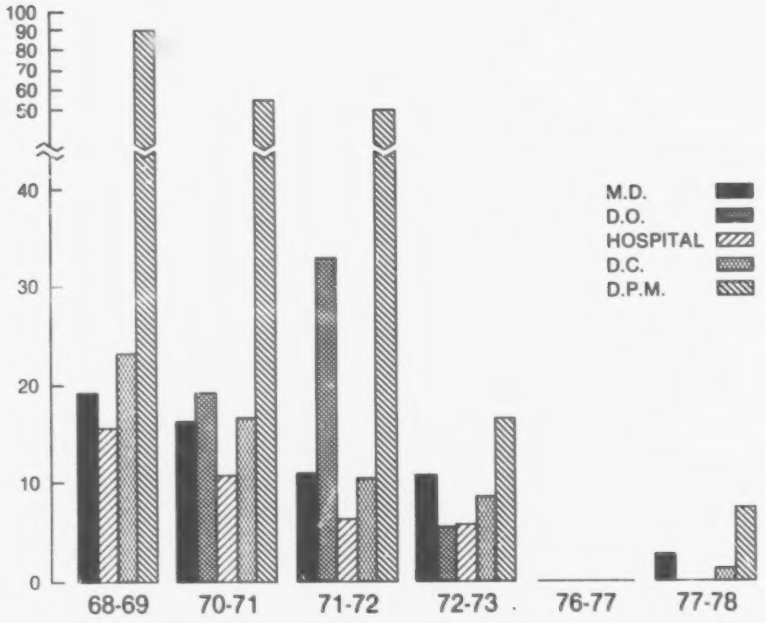

Figure 2. Percent of noncompliances for filtration by type of facility

Table 1. Patients radiographed by year in Oregon

	1975	1976	1977
Hospitals	718,250	1,074,335	938,625
Private practice MD/DO	1,340,660	886,640	770,210
Dentist	1,959,320	1,752,910	1,830,452
Total	4,018,230	3,713,885	3,539,287
Estimated State population	2,299,000	2,347,750	2,396,100
Percent of total population x-rayed	174.8	158.2	147.7

PLANNING REGULATIONS can COMPLICATE your LIFE

Jerome H. Shapiro, M.D.
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City of Boston Department of Health and Hospitals

When I was very young, there was a ditty that went as follows (and some of you who are almost as old as I may recall it). "It's delightful, it's delicious, it's delovely" and it went on and on. I can only respond that as far as governmental guidelines and governmental rules and regulations, and everything that goes along with it, as a Chairman and Director of a Department of Radiology, it's not delightful, it's not delicious, and it's not delovely. As a matter of fact I give you my own alliteration--it's destracting, it's distressing, it's demeaning, it's debilitating, it's depressing, it's destructive, it's demoniacal, and finally it is awfully discouraging. I accept the fact that regulators must regulate, just as physicians must practice medicine. But what I see as I look backward and anticipate by trying to look forward is that regulations never seem to result in the perfection that the regulators intended. Therefore, the regulators must each year propose new regulations to reach some form of perfection.

The ultimate, I assume for health care, is some form of public control but at the same time one hears that it is necessary to deregulate the trucking industry and to deregulate the airline industry because they have now been overregulated and therefore restricted in their growth opportunities. I suppose that the health care industry is now in for its turn to be regulated and somewhere down the line there will be a group of planners that will say that it is now moribund making it necessary to begin the deregulation process. All of these seem to go in cycles and change seems inevitable.

I would hope that you might have a little sympathy for me. I am a somewhat endangered species. As a Chairman I get it from my own staff which includes the radiologists, the residents, and the technologists. I occasionally even get it from patients and I certainly get it from the rest of the medical staff and all of the time from the administration. On top of that there is a medical school which is concerned with education and has its own set of rules and regulations. There are local regulatory activities as there are at the State and Federal levels. Then there is the awesome JCAH with its accreditation process. When an inspection is scheduled in our institution the entire institution and its staff become totally immobilized for months prior to the inspection visitation. One wonders how it is possible to deliver any health care until the JCAH has come through and inspected the institution.

I think as I have heard some of the presentations, that it is necessary every once in a while to take a withdrawn perspective--that all of this does not occur in a vacuum. We have gone through, and are still going through, a dramatic, social, political, ethical, religious, moral, and anything you want revolution. The end is certainly not in sight. These changes have disrupted just about anything that is tangible. One finding which puzzles me is the seeming development of what is an essentially lawless society. One of my favorite pastimes is watching automobile drivers. In the State of Massachusetts this is a fascinating but at times dangerous experience because they do all sorts of strange things. They make right turns from the left lane and left turns from the right lane. It may be possible even to make a U turn in which you find a car in a head-on collision setting. Stop signs, red lights, and caution signs are all ignored. If you ever want to see a great tourist attraction come to Massachusetts and watch the drivers drive. I used to get very angry but I finally have come around to have some peace with myself and them. I just think they are pent up, they are frustrated, they are angry at everything that is happening around them and the only time they have any sense of power is when they get behind the wheel, put down the pedal and away they go without restraints and caution to the wind.

Perhaps it is time, instead of talking about increasing the rules and regulations, to perhaps think that we might accomplish more by changing the behavior of individuals through some form of motivational method in an effort to proceed along a line which would permit us to deregulate rather than increase the regulatory process. This however may be wishful thinking and is probably unlikely.

What else do I see around me? It seems that the space available for our work is getting more restricted and our budgets have remained static. In our two institutions we have seen the acquisition of a large administrative staff including a number of health care planners. In fact, we have two individuals in each of the two hospitals that do nothing but deal with regulatory activities, filing certificates of need, working our various programs with all the ramifications of regulatory activities at all levels. We now have three legal counsels that are also involved in this same type of activity. Even my own administration tells me that I really do not know how to administer any more. They say that I should go to the Harvard B school because I don't speak the right language. I don't talk in administrative terms or in current administrative jargon--you know the terms such as cost effectiveness, cost control, zero growth, and so forth. We are asked by our administrators that as radiologists we ought to stand in the doorway and refuse to do the unnecessary x-ray examinations. Therefore, we wouldn't need additional x-ray machines or additional radiologic technologists. Sonehow or other, and it has taken me a long time to come around to it, I just don't think the health care industry is subject to the type of teaching that comes out of the Harvard B School.

Let me quote from some comments that were made by Shelton Leonard who is manager of regulatory activities of the General Electric Company. Apparently, they find it necessary to put someone like this on their payroll.

"The second contributing factor in the present-day community hospital and its mode of operation has been likened to that of a unique type of hotel that provides the following:

1. Provides or can provide, on demand, all its services around the clock every day.
2. Maintains a high staff to customer ratio to provide this intensity of service.
3. Maintains large investments in facilities and equipment required by the staff that must be available at all times to fulfill the needs of its customers.
4. Cannot refuse service to a customer based upon the ability of the customer to pay for the service.
5. Provides admission whether or not the customer was scheduled.
6. Copes with customers who stay for indeterminate periods of time.
7. Usually is not paid for by the customer but by one or other combinations of several third parties."

Now is that any way to run a business? But those of us who run departments of radiology have been doing it for years. Although I would admit that sometimes we have not been as efficient as possible we have however been rather effective in delivering high quality health care.

Now I am being told more and more "Dr. Shapiro, you really don't understand the planning process. We are planning health care and you are constantly taking about delivering health care." And I said, "I want to plan with you." And of course the reaction is, but you are not compliant enough, you are too resistant, you are too intransigent.

And now I would like to get off my chest some of my recent activities with what used to be called CON and now DON (determination of need). This type of involvement is extremely time consuming, its effort, it takes my away from other things that I think might help patients or educate medical students and residents. It pits me against a group of health care planners and I think that is unfortunate. We have now gone through probably the most painful series of hearings of DON for CT body scaning units in the Greater Boston area. Meetings at the HSA level have been occurring every Wednesday from 6:00 p.m. to 12:00 midnight. At the end of each of these sessions where my colleagues with their hospital administrators and health care representatives sit around the health care planning agency committees. We are usually silent after listening to statements and presentations that are made--some of which are half true, some of which are just not true. I have seen the advisory staffs to the committee acting out in an arrogant manner, admitting that they lack the methodology but proceeding to utilize data and apply this in a rigid manner toward the decisionmaking process. They are sometimes unrealistic. They sometimes foster the agressive competition between institutions which is most destructive. They have involved themselves in internal institutional policies which are beyond the province of their responsibility. When challenged as to whether or not that is within the scope of responsibility, the answer is "If you don't like it try litigation." I am never referred to by name, neither is the institution. I am called a provider or the applicant. I am something that is anonymous that is managed by a management group that is determining how health care is going to be delivered. However, I remain the individual who is going to have to be the key member in providing this health care for human beings.

As I look around the table at the HSA meetings I find a group of interested and intense individuals who are consumer oriented. Some of them unfortunately have not been informed. Some of them take unto themselves in a very intense manner issues which may be irrelevant and in some instances feel that they must lead a campaign to clean up the health care problem. And they certainly with each statement indicate that it is in a terrible mess and it just can't wait until they can resolve it as quickly as possible. They have set up what I think are impossible guidelines, namely that a CT scanner will operate 76 hours a week or you will not be getting a scanner, that you will work 9 hours a day in a general diagnostic department, 5-1/2 days a week and I contend that it just cannot be done. They insist that you will fluoroscope one patient every 15 minutes and I just can't do that. The reaction to all of this, and I have seen it in our own institution as well as other institutions, is that you have to survive. You begin to play the game in an adversary relationship against the health care planners. You begin to use their terminology. We will prioritize, we will massage the data, we will reassess our management, we will realign ourselves with other neighboring institutions, we will go out and get more business even if it may mean unnecessary examinations in order to make our application in compliance with what the process requires.

In the introduction, the chairman really did not give my all of my three hats. In the center we have a medical school and on either side two hospitals, one the University Hospital and the other the Boston City Hospital. After 15 years of effort in our department we have finally integrated the radiology program so successfully that we have a single DON application with both institutions jointly sponsoring this application. The advisory staff to the HSA ripped the application apart realizing that in their efforts they were going to destroy 15 years of internal planning. I would submit that they had once again involved themselves in internal hospital policies that are far beyond their realm of responsibility or jurisdiction.

Each week at the HSA meeting as our application comes up and is discussed, it is usually the highlight of the evening. It is held off till about midnight and everyone stays to witness the performance. We have survived a series of close votes some in which the Chairman has had to cast the deciding vote. I am not certain that this is the way to make decisions in health care planning but that is the way the scenario has been going. And last week was the final meeting before we go to the full-State Public Health Council. For me it was the most depressing meeting because when our application came up there were three hands raised to speak against it. One, a white woman, one, a black man, and the third a Puerto Rican woman. Ordinarily, I would have thought that these represented our very own constituents who are rising to support the application. Instead, they requested time to speak against the application. One spoke because they thought that the Boston City Hospital should not put its tax dollars into this complicated technology which could result in a rise in the tax rate. This individual thought that the rich people should buy the machine and she would help in figuring out something that might be more appropriate for the poor people. The second individual thought that the entire application was part of a national conspiracy of making unsafe machines that would be used on poor people and harming them unnecessarily. The third individual raised the issue of the safety of computers. The chairman thought he might have reference to the x-ray component but the individual said no he actually meant the computers and wanted to be reassured that computers had been tested in animals--it was at that point that I know that we were in serious trouble.

Somehow or other our very own constituency did not seem to understand what it was we were trying to do. We had not been able to get to them sufficiently to educate them, to emphasize to them what our objectives were. At the end of the evening we finally came through with another squeaker, 6 to 4 and go forth once again I hope for a final and ultimate decision. But in the process, the animosity created by the advisory staff serving the committee and our institution has been so intense that it has created an adversarial relationship. To me that is not health care planning. As soon as this is over we go in with a new DON to replace two RNF rooms. I am going to have to look at the same faces all over again.

Part of this ongoing process is a public attitude toward medicine. Public and repeated surveys seems to be saying that they are fairly satisfied with medical services. They are concerned about availability, they are concerned about its cost. Somehow or other in the equation quality never seems to get discussed. This is the problem that the consumer must face up to. It is certainly the problem that we have. There is no way in which we can shut the door on medical progress. Certainaly in radiology, you have witnessed explosive technological progress in the last decade. It crosses through nuclear medicine, ultrasound, and computed axial tomography.

But society somehow or other doesn't always cooperate and appreciate the progress. Let me read you this news item. I am sure you have seen it. A plastic surgeon said he will appeal a jury award of $854,219 to a woman whose belly button he replaced. "She beat the system," said Dr. Howard Bellum, "but I will appeal. It was the most absurd amount of money for a belly button. People who lose arms and legs only get $300,000." However, the owner of the offcenter umbilicus, 42-year-old Virginia O'Hare, said, "a centered belly button is a valuable feminine attribute. Singer Cher made millions on hers." O'Hare underwent a 1974 operation for a tummy tuck. After Bellum promised her a nice flat belly, instead she says she woke from the anesthetic to find that her navel was off center by 2 inches. "The belly button was no longer normal. It was a largely deformed hole in her stomach and its scar was of significant thickness," her attorney, Theodore Creekman told the State Supreme Court jury of 4 men and 2 women. in her complaint O'Hare said her sex life had suffered and her sense of self worth was damaged because of the noncentered navel. She also claimed her ability to function as owner of a Poughkeepsie employment agency was impaired. The position of her navel has since been corrected by another doctor. After an 8-hour trial the jury debated 4 hours. On Wednesday the court awarded O'Hare $100,000 for pain and suffering, $750,000 for loss of earnings (I don't know why), and $42,019 for medical expenses. This story is hardly amusing but it reflects on the society around us. This is our society. As an earlier speaker said, "I have met the enemy, I accede, but I am not sure it is they or we. As always, it is this society in which we live." It is this society which sets these values. And this is the society which I think you will ultimately determine where it is we are going to go when it comes to the practice of medicine, and particularly the practice of radiology.

Let me finally conclude with a couple of perhaps positive notes. I am not against health care planning, I don't despise health care planners, they have only one head and they dress as I do, and they look like I do and they are reasonably intelligent individuals. We just differ basically on what the problem is and how we are going to reach some sort of a solution. May I suggest that all of us have got to come down to reevaluate or assess our priorities.

How do we determine and provide quality in radiologic examination? How do we provide an adequate quantity of radiologic examinations for everybody who needs radiologic examinations, and then how do we determine the efficacy of the studies which we perform? The answers unfortunately, are not here but there are proponents and opponents who would give us, unfortunately, biased views of what they think are the correct answers. I might even say why not regulate overeating, smoking, and alcohol abuse and we would save a lot of lives, an lot of dollars. That unfortunately is not practical. I think we in radiology will repeatedly come forth even from Washington that we can't do everything and therefore we have to allocate our resources, and that to me is interpreted as rationing of radiologic services.

I began this talk with an alliteration and will close in the same manner. Instead of 3 R's I will give you 4 R's. First R, I think we have all got to be responsible. We have to be responsible for what we do and we must take responsible positions that we can defend when it comes to delivering what we think are good radiological services.

The second R is responsive. There is a big society out there. It is extremely mobile in a state of tremendous unrest. We have got to listen to that society so we can respond to it intelligently and articulately. Third, we have got to be resourceful. We have got to be able to do things with the least amount of radiation and somehow or other come up with the best results. Lastly, and this applies to me, we have got to be awfully resilient because in going ahead, it is going to be awfully rocky.

THE IMPACT of REGULATIONS on the HOSPITAL PHYSICIST

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Department of Radiology
University of Colorado Medical Center

I appreciate the opportunity to speak to this group of radiation program directors on the topic of "The Impact of Regulations on the Hospital Physicist." The major difficulty I faced in preparing this presentation was identifying where to start and what topics to cover. This difficulty reflects the problem that the impact of regulations on the hospital physicist has been not just significant, but in actual fact overwhelming.

In most cases, the hospital physicist is a radiological physicist with responsibilities that are oriented primarily to a department of radiolgy. The principal objective of the radiological physicist is to ensure that radiation is used in a productive and efficacious way in the treatment of cancer and in the detection and diagnosis of disease. Also within the physicist's responsibilities are the provision of reasonably safe working conditions for employees of the institution, and the delivery of patient radiation doses that are as low as possible consistent with adequate treatment in therapy or adequate information in diagnosis. These responsibilities place the physicist in the direct firing line of the many Federal and State agencies that are dedicated to compiling a stack of regulations that is reaching ominous proportions with no end in sight.

IMPACT OF REGULATIONS ON THE HOSPITAL PHYSICIST

In the interest of time, I shall confine my remarks to two areas of regulations that are particularly troublesome to hospital physicists. The first is the ALARA concept of radiation exposure. This concept states that in any institution in which ionizing radiation is used, exposures to individuals should be kept as low as reasonably achievable. Hospital physicists have no difficulty with ALARA as a concept; in fact, we have been adhering to it within our own facilities for years, and would continue to do so irrespective of its recent prominence within regulatory agencies as a viable concept for their attention.

The difficulty with ALARA is not its usefulness as a concept; the difficulty arises when it becomes a regulation. It is true that to my knowledge ALARA has never been published as a regulation; instead, it appears in the guise of a "regulatory guide" or a "guideline," as for example in proposed Regulatory Guides 8.10 and 8.18 published by the U.S. Nuclear Regulatory Commission. In Regulatory Guide 8.18, however, the Commission is careful to point out that although ALARA is not exactly a regulation, it will be used in the evaluation of license applications for the use of radioactive byproduct material. In addition, the Commission notes that ALARA will be applied to determine compliance with the Commission's concept of safe working practices during the inspection of a licensee's facilities and radiation program. Hence, ALARA really is a regulation, and is particularly troublesome because it requires a subjective appraisal of whether a particular facility's procedures and working conditions result in exposures that are "as low as reasonably achievable." Furthermore, this subjective appraisal is to be made by members of the Commission who review license applications and conduct facility inspections.

In any facility in which radiation is used, exposures to personnel can always be reduced, although usually at some financial cost and often with some reduction in diagnostic information about the facility's patients, or with some interference with the facility's ability to deliver curative and palliative doses to cancer patients. The ultimate radiation dose that is reasonably achievable is no dose at all; when the facility has decided simply to discontinue radiation services and close its doors to the needs of patients. The real question is "Who decides what dose is reasonably achievable for a particular institution?" The answer is "The U.S. Nuclear Regulatory Commission." This authority by the Commission places the hospital physicist in an untenable position, because he is responsible for implementing procedures in the institution which are consistent with the Commission's interpretation of ALARA even though he has no firm guidelines of what that interpretation is with respect to his own facility. At the same time, the physicist is required to help his institution conduct procedures that serve the needs of patients within the financial and manpower constraints imposed today on every health care facility in this country. In my opionion, a more untenable position for the hospital physicist cannot be imagined.

I wish next to describe the hospital physicist's perception of one of the products of this Conference, namely the Suggested State Regulations for Radiation Control. As some of you may know, I have been a rather vocal critic of past issues of this document, principally because they have reflected a naive appreciation of radiation exposure problems in a clinical environment, and because they have evolved from draft documents into State regulations without proper review by persons outside the regulatory environment. In the latest (1978) draft of the Suggested State Regulations, some of the problems of earlier drafts have been partially resolved. Still, other problems remain, and it is these problems that I wish to address in the remainder of this presentation. These problems could be resolved very simply if the Conference would only solicit the advice of hospital physicists in drafting the Suggested State Regulations, and not insist on confining input to the regulations to members of the National Conference and other representatives of regulatory agencies. By soliciting the consultation of hospital physicists as you prepare the draft documents, you could spare both yourselves and many hospital physicists a lot of time and effort.

In the interests of time, I shall confine my remarks to only one part of the 1978 version of the Suggested State Regulations. This part is Part F: X Rays in the Healing Arts.

Critique of Part F: X Rays in the Healing Arts in the 1978 Suggested State Rules and Regulations for Radiation Control.

Page	Comment
1	Assembler by definition would include any hospital physicist or engineer who works on an x-ray system.
10	Technique charts such as those specified are not applicable to automatic exposure control, anatomical programmed radiography, or organomatic x-ray systems.
10-11	Under what exposure conditions is the lead equivalence of protective devices to be determined?
12	Recordkeeping such as that required for all persons involved in using mechanical holding devices during roentgenography is burdensome and has no apparent objective.
12	Placement of the personnel monitoring device on the collar is inconsistent with the opinion of many recognized radiation experts and presents difficulties in retrospective estimates of whole body or fetal dose.
13	An x-ray log of the type envisioned would be time consuming and would duplicate departmental records for purposes which are not stated in the regulations.
14	The review and approval of floor plans and equipment placement places the regulatory agency in direct competition with hospital physicists.

Page	Comment
18	Requirements on technique indicators are not compatible with certain automatic programmed radiography and time sharing x-ray systems.
21	No phantom is specified for fluoroscopic exposure rate measurements, and reasons are unclear why movable grids and compression devices should be removed.
23	In most cinefluorographic systems, the indicated mA is meaningless, so why must it be continuously indicated?
24	In some angiographic techniques, the examination technique precludes compliance with regulations for attenuation of patient scatter.
27	Permanent mounting of exposure switches precludes communication with patients in many departments, including my own.
28	The requirement of a minimum exposure time no greater than 1/60 sec, or a minimum mAs no greater than 5 mAs, is not achievable by many older x-ray systems. This problem exists also for many of the other requirements, such as a 30-cm minimum source-skin distance for portable x-ray systems, and a visible and audible indication of x-ray exposure and its termination.
29	The requirement that addition of one certified component brings an entire x-ray system under a series of compliance constraints presents severe potential problems for older x-ray equipment.

As general questions regarding regulations of the sort proposed, one might propose the following:

1. "Who is supposed to check the compliance of diagnostic x-ray units with all of these requirements, and how often should these checks be made?"
2. "Are there a sufficient number of hospital physicists to evaluate compliance for all x-ray units in this country?"
3. "What is the cost effectiveness of a program to ensure compliance with the Suggested State Regulations?"

A few comments are appropriate also concerning those parts of Section F which are addressed to radiation therapy units. For example:

Page	Comment
45	Specification of the dose equivalent for leakage as less than 0.1 percent for x-ray leakage or less than 0.5 percent for neutron leakage compared to the maximum dose equivalent of the useful beam on the central axis is unreasonable in light of current discussions at the national level on the issue of neutron contamination of high energy x-ray beams.
46	How would you propose to display the wedge orientation at the control panel, especially when the orientation depends on collimator rotation?
50	If the pre-selected dose monitor must be reset after termination of treatment, does this mean that the thumbwheels on a linear accelerator must be reset even if the same treatment is to be delivered to the next field? Similar comments can be directed to the timer section on page 51.

Page	Comment
50	The specification of 102 percent for secondary dose monitors is much more restrictive than the current equipment limit of 115 percent.
51	The restriction on this page would prohibit obtaining port films for conditions under which electron therapy is delivered.
55	Why specify calibration of an accelerator in air and at various depths in a phantom, when in fact calibration exclusively in a phantom is the standard protocol?

With all the interlocks and safety features specified in the proposed Part F for x-ray treatment machines, has any thought been given to the cost of modifying existing accelerators to accommodate these requirements?

I could continue the rest of the afternoon to describe problems with the Suggested State Regulations and similar products of other regulatory agencies, but perhaps the ones that I have mentioned provide enough insight into the difficulties of the hospital physicist in coping with the imaginative productivity of the regulatory bureaucracy. In 1976 alone, 57,027 pages of fine print were required in the FEDERAL REGISTER simply to describe the regulative productivity of the Federal bureaucracy, without inclusion of any of the regulations developed by State and municipal bureaucracies. As stated by William Simon, former Secretary of the Treasury, in his recent book *A Time for Truth*, "This is a *disease* of government; it is not government."

COST/BENEFIT of the DIAGNOSTIC X-RAY STANDARD--A SECOND LOOK

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Bureau of Radiological Health, FDA

The work I am reporting on today is a reanalysis of the costs and benefits associated with the Diagnostic X-Ray Standard. It continues a project started by Drs. H. Rudolph and T. Shope of the BRH staff. It is based on the third draft of a cost/benefit analysis that was circulated to the public for comment in January 1979 (1). Because the draft report is comprised of some 70 pages, a detailed discussion at this time is inappropriate. I will therefore describe the major assumptions that went into the draft report, summarize the results, and indicate some of the public comments that were received.

The Radiation Control for Health and Safety Act of 1968 authorized the establishment of performance standards for electronic products that emit radiation. Under this authority the Food and Drug Administration established the Diagnostic X-Ray Performance Standard (21 CFR 1020.30). This was published in 1972, and became effective on August 1, 1974.

Concurrently, in fulfilling part of the requirements of the National Environmental Policy Act, an Environmental Assessment Report (2) was prepared in 1973 and 1974. The bulk of this report was a cost/benefit analysis of the standard and of the associated policy on the assembly and reassembly of diagnostic x-ray systems, known as Section 1000.16.

The standard provides that documentation be provided to FDA on all certified x-ray systems that are assembled. This information has provided a data base not available in 1973; this new data together with the experience gained by the administration of the standard, provided the material to prompt a reevaluation of the original cost/benefit analysis. This intention to reevaluate is reinforced by the Bureau's policy of updating the standard to take account of changes in the industry and anticipated the subsequent executive policy of reassessing existing Federal regulation.

The analysis reaches its conclusions by developing a model of the x-ray market and uses this model to evaluate the cost of the standard. The benefits of the standard are estimated using data from the 1970 XES (3). Both the cost and benefits are compared on a dollar basis.

The reporting requirement of the standard has created a data base from which we can draw conclusions about the x-ray market. A second source of information is the annual reports of State Health Departments on x-ray installations (4). The data in Figure 1, derived from the State data, illustrate the total number of diagnostic x-ray systems in use by year since 1966. This excludes dental systems. The graph shows a slight increasing trend in the number of medical systems in use, a little less than 2000 per year. This increase is misleading, however, since the early data are quite sketchy. We believe that a significant portion of the increase shown may be because of better reporting in recent years. For the purposes of this analysis we assume the number of medical systems in use is 125,000, and is remaining roughly constant.

There have been several effects that have slowed the growth of the number of new x-ray systems assembled; for example, cost containment and the advent of computed tomography (CT) (Fig. 2). Whole-body CT machines are much more expensive than the x-ray equipment that they replace. Given constant or decreasing amount of capital available to purchase x-ray equipment, the growth of CT machines in use indicates a decreased availability of funds to purchase conventional x-ray equipment. Our own reporting data (Fig. 3) indicate a leveling off of the number of new general purpose systems being installed at about 800 per quarter.

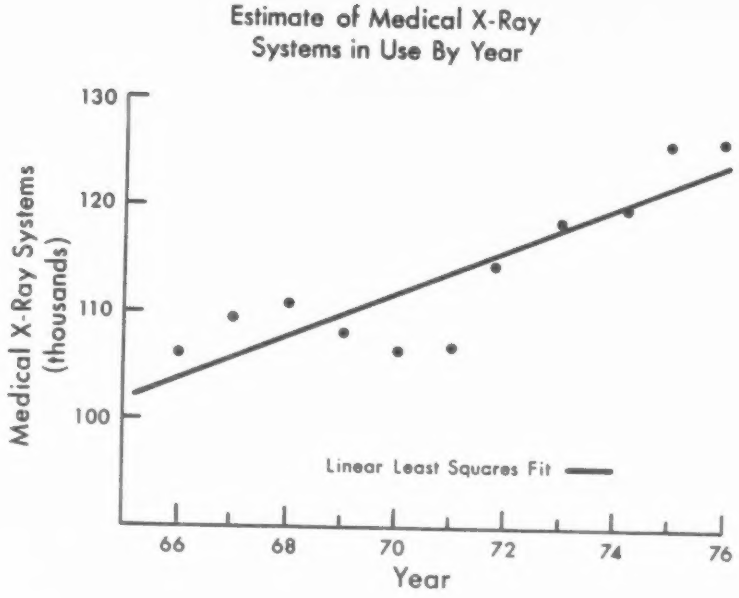

Figure 1

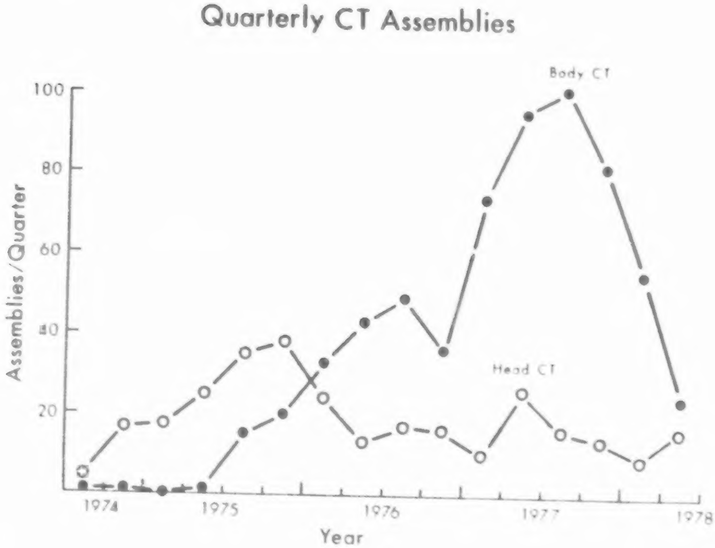

Figure 2

Based on data derived from a study on antiquated x-ray equipment (5) conducted by the Public Health Service, the assumption is made that the average life of a diagnostic system is 20 years. This is a highly variable value, depending on the workload of the system, its use, the quality of manufacture, maintenance costs, and other factors, such as cost containment which now limits replacement of existing units. For example, the decrease in number of CT units assembled shown in Figure 2 is probably due to the effort to control their proliferation.

Quarterly Stationary, General Purpose Assemblies

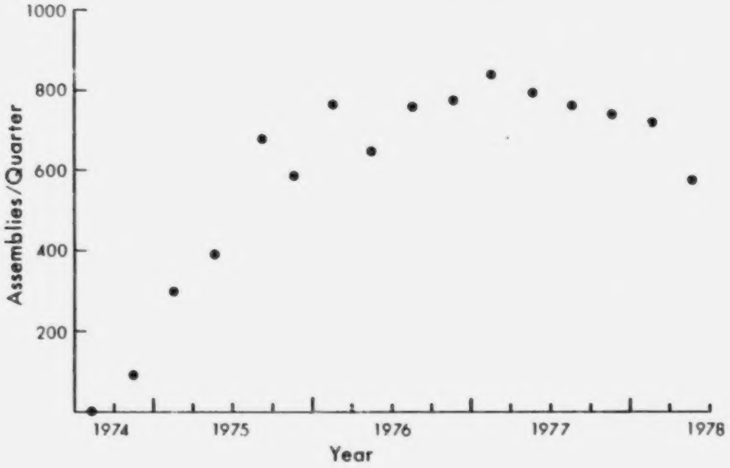

Figure 3

Generally a complex piece of equipment such as an R/F system in a high workload facility will not last as long as a simple chest unit in an office. Various components of this system will, however, be used in progressively less rigorous surroundings as other components wear out. The generator, for example, is one component that should last a long time.

Besides the new equipment market there exists a significant used market. Based on surveys of manufacturers, dealers, assemblers, and a few State Health Departments, we estimate this to be between 15 and 30 percent of the new systems sold. These systems are generally between 5 and 15 years old when resold. In the analysis we assume a first sale life of 10 years and a used life following resale of 10 more years.

It should be noted that for the number of systems assumed in use (125,000), the yearly replacement rate from assemblers report data is 5 percent or about 6000 per year. This corresponds to our assumed 20-year lifetime.

A spinoff of this particular part of the analysis is in the area of policiy on assembly and reassembly. The model has indicated that the provisions of paragraph 1000.16, which would take effect on August 1, 1979, would not do the job that the Bureau envisions; the removal of poor x-ray equipment from use. Only 1-2 percent of the systems in use would be effected on a yearly basis, and these would not necessarily be the poor units. Other aspects that we originally contemplated, such as the availability of used certified equipment, have not taken place. For these and other reasons, the Bureau has therefore taken action to amend these provisions.

Major sources of cost have been assigned as shown in Table 1. The first of these is the cost of administration of the standard to Federal and State governments. This type of cost does not show up directly as a price increase for new equipment.

Table 1. Costs of the Performance Standard

- Administration of the Performance Standard
- Recordkeeping and Reports
- Performance Requirements Other Than PBL
- PBL Requirements

The last cost on the list is that due to the requirement for positive beam limitation (PBL) on stationary, general purpose equipment. A survey of manufacturers conducted in 1976 showed that, depending upon the sophistication of the PBL system, the added cost per system of PBL ranged from $1,000 to $6,000. We estimate that the average price increase because of this requirement has been about $4,000. In addition, we have included in our cost estimate for PBL an additional cost for the possibility of increased maintenance of the PBL system.

The second and third costs are the most difficult to evaluate. We have attempted to obtain data from industry, but industry representatives have been either unable or unwilling to give us any hard data. There have been several guesses made that range from 2 to 17 percent of wholesale value for the total of these two costs. One of the reasons for distributing the draft document was to attempt to have industry respond with their data and comments. Figure 4 shows a plot of the wholesale price index for the years 1963 through 1976 as well as the price indices for all industrial commodities and for a typical general purpose x-ray radiographic system. These data were obtained from the Bureau of Labor Statistics (6). The data for the medical x-ray system are corrected for the price increase because of PBL so that any increase is the result of other factors such as the standard. It can be observed that all these curves have the same general trend (upwards) and closely follow one another for the years 1973 through 1976. That is, no significant difference exists for the medical x-ray system index. This is only one type of system. It is only an indication of what has happened. For this analysis, we have assumed that the price increases not resulting from PBL are 5 percent of the retail value of the x-ray system. Some of the industry comments contend that this 5 percent value is an underestimation of the actual cost. Data to support this contention, however, have not been provided. We, therefore, are not persuaded to change this value.

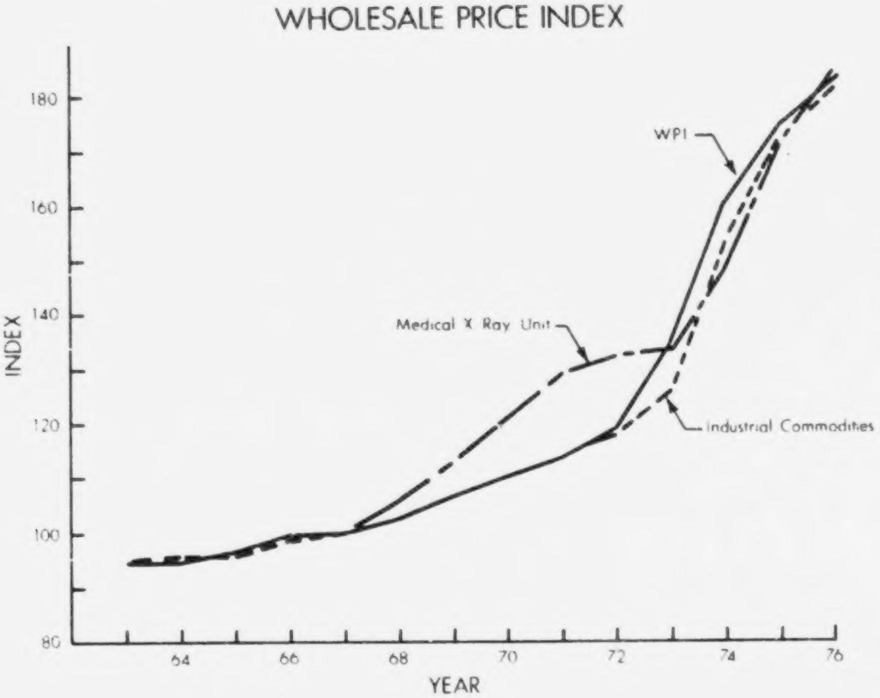

Figure 4

The main benefit of the standard is in the reduction of exposure to the population. This results from three major effects: (1) the improved field limitation and alignment acquirements (PBL), (2) reduced repeat examinations because of calibration and reproduceability requirements on kV, mA, time, and other machine parameters, and (3) elimination of defects before introduction into commerce through quality control. In assessing these benefits, there are two obvious difficulties. First, the difficulty of estimating the exposure reduction, and second, the difficulty of comparing an exposure reduction with the number of dollars expended in achieving it.

To estimate the exposure reduction achievable from the field limitation and alignment requirements of the standard, we have relied on two calculations done by BRH staff, using as input the 1970 X-Ray Exposure Survey. Both of these calculations used the 1970 XES exposure data and image receptor size data to calculate a dose savings that could occur if the x-ray field and image receptor sizes were equal. In one study (7), the genetically significant dose savings was calculated, and we have used this as a measure of the genetic damage that could be avoided. In the other study(8), the active bone marrow dose savings was calculated and we have used this as a measure of the somatic damage that could be avoided.

In addition, we have attempted to calculate the dose savings that result from some of the other requirements of the standard. This was not done in the original cost/benefit analysis. This is generally much more difficult because the data base is extremely poor. We have, however, made some educated guesses to obtain gross estimates. It appears that the dose savings possible through these other features can be as large as that possible through appropriate field limitation and alignment. However, because of the fuzziness of the calculations, we have chosen to use a dose savings equal to 1/3 of the field limitation and alignment dose savings. This is probably a somewhat low estimate.

To compare benefits with costs directly, it is necessary to try to place an economic value on radiation dose saved. This is a somewhat chancy venture at best, and in our paper it has been the target of several comments. There are numerous estimates of the dollar cost of a person-rem in the literature. Table 2 shows a sampling of these. The estimates try to determine potential loss of income, cost to society, hospitalization cost, and risk of

Table 2. Estimates of cost of unit radiation dose

Author	$/person-rad	Literature reference
Cohen	$250	(11) Health Physics, 19 (1970), 633.
Hedgran & Lindell	$200	(12) Health Physics, 19 (1970), 121.
Dunster	$ 10	(13) Health Physics, 19 (1970), 121.
Lederberg	$100 - $600	(14) Bull. Atom. Sci., 27 (1971), 43.
Otway	$200 - $250	(15) Proceedings Mid-Year Symposium of HPS, Richland, Washington (October 1971), 410
BEIR Committee	$ 19 - $191*	(7) The Effects on Population of Exposure to Low Levels of Ionizing Radiation, NAS Report, November 1972.
Sagan	$ 30	(16) Science, 177 (1972), 487.
Cohen	$200	(17) Health Physics, 25 (1973), 527.
Nuclear Regulatory Commission	$1,000	(18) 10CFR Part 50. (26 FR 12518, December 27, 1961).
Lindell	$100	(19) Health Physics, 31 (1976), 265.

*This value corrected to reflect health care spending for 1976 rather than for 1970, ($638 per person rather than $400 per person for the U.S. population used by the BEIR Committee).

harm in arriving at a value. As you can see, there is little agreement over the value of this parameter, the estimates here ranging over two orders of magnitude. The methods used in this assortment of references range from pure guesswork (the extreme estimates) to real (semi-scientific) calculations. I am sorry to say that I have nothing new to add. The BRH for the present has chosen to use a figure of $100 per person-rem as the value of genetic or somatic dose avoided. This is to be used for program planning purposes with the full awareness that science is somewhat absent from this choice and that use of such a parameter is for comparison of program alternatives.

In this calculation, we have discounted benefits accruing in future years at a rate of 10 percent/year to the year in which the costs occur; i.e., the year the x-ray system is purchased. This was done to make the comparison of costs and benefits more valid. It is a generally accepted accounting technique and mandated by the Office of Management and Budget. In effect, this reduces benefits by about a factor of 2. We have also: (a) used weight factors for the workload as a function of age of the system and (b) assumed a constant utilization of x rays for a constant size population.

The results of this calculation are shown on Table 3. The lower benefits and costs in the first few years of standard result from lower x-ray equipment sales. This was probably because of a buy-in of uncertified x-ray systems prior to August 1, 1974. As you can see, the benefit/cost ratio is about 4 or 5 when things settled down. The data in this table might be termed a best estimate. Figure 5 contains curves determined from a sensitivity analysis of the benefits of the field limitation and alignment requirements. Here, the lower and upper curves represent the possible extremes for all parameters except the economic cost of radiation dose. If the manufacturers' comments are correct, we have underestimated the cost of the standard and the benefit/cost values would be reduced accordingly.

Table 3. Costs and benefits of the performance standard

Year	Cost (millions)	Benefit (millions)
1975	$44	$ 77
1976	$38	$145
1977	$39	$161
1978	$43	$194
1979	$43	$194
1980	$43	$194

As indicated earlier, a spinoff of the modeling process has been a reevaluation of the effects of the policy on reassembly of diagnostic x-ray systems which will become effective on August 1, 1979. This policy will require, under certain conditions, that only certified x-ray system components can be reassembled to form a new x-ray system installation.

In a Notice of Proposed Rulemaking (44 FR 22755) published on April 17, 1979, the Bureau listed three reasons for proposing a change in the policy. These were: (1) of 100,000 uncertified systems in use, only 1100 to 2600 per year would be affected; (2) for those systems affected, there would be a significant economic impact; and (3) the benefit/cost ratio to be derived was less than 1 and significantly less than that of the standard.

The major costs of this requirement as used in the analysis will be the loss of resale value of the uncertified component to the seller and the necessity of buying new, rather than used, components for the buyer. The benefit calculation is similar to that for the standard with the exception that benefits are calculated only for a 10-year period.

Estimate of Annual Benefit
from
X-Ray Field Limitation Requirement

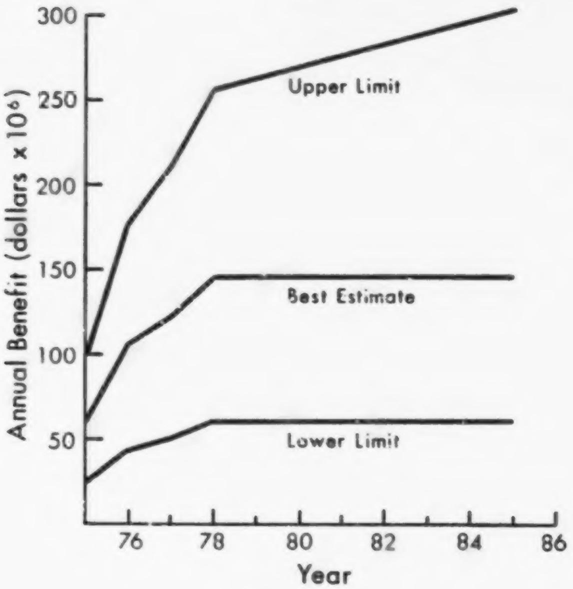

Figure 5

This particular part of the analysis has received extensive comment, mainly commenting that we have overestimated the costs. We are currently revising those figures so I am not showing final data.

The data from the third draft prior to comment is shown in Table 4. The two sets of columns define a range for the analysis, within which we believe the true impact lies. The high market estimate assumes that 30 percent of the systems sold each year are used. In addition, it is assumed that none of the components of the systems that would normally be sold as used are certified; i.e., complete loss of resale value and greatest depression of the used equipment market. The low market estimate assumes that 15 percent of the systems sold each year are used, and that one-fourth of the value of these systems is in certified components.

Table 4. Costs and benefits of 1000.16 (d)

	Low market estimate		High market estimate	
Year	Cost (millions)	Benefit (millions)	Cost (millions)	Benefit (millions)
1980	$34	$20	$121	$47
1981	$32	$17	$112	$47
1982	$29	$16	$101	$40
1983	$25	$15	$89	$35
1984	$21	$12	$76	$29
1985	$18	$11	$64	$25

Under the set of assumptions made, this requirement would not appear to be cost-effective. As indicated, however, this last conclusion has been questioned. it is not however crucial to our decision to modify the policy.

In summary, this paper is being presented to illustrate an approach to analyzing the costs and benefits associated with a regulation. It is based on a draft report concerning the diagnostic x-ray performance standard and the associated policy on assembly and reassembly of diagnostic x-ray systems and therefore does not represent a final BRH position. Based on the darft, study, the diagnostic x-ray performance standard appears to be cost effective while the policy on assembly and reassembly does not appear to be cost effective.

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WHAT SHOULD/SHOULDN'T the RADIOLOGIST be ASKED to do?

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As a practicing physician in radiology, I am sure my perspective is different and I shall try to express this by reviewing a problem which I have to deal with at my level of responsibility. I am responsible for direction of radiological imaging for the Swedish Medical Center. My associate, Charles Seibert, a neuroradiologist, has worked with me in this area and I would like to recognize his contribution. The example I have chosen occurs when we radiologists are consultants to the primary physician often becoming involved in his problem of the differential diagnosis of hysteria versus organicity in such common diagnoses as headaches, neck or back pain, and dizziness.

Unfortunately, radiological examinations cannot be relied upon totally to differentiate patients with hysteria from those with organic disease. Patients with hysterical symptoms may have positive findings, but patients with proven disease may have negative radiological exams.

For example, our referring physician, seeing a patient with a suspect neurological disorder, has a myriad of potential tests available. In radiology, available studies often ordered include skull and cervical spine, tomograms of the cervical spine, petrous pyramids, flexion, extension dynamic studies of the spine, computed tomography, nuclear radiologic studies, isotopic brain flow scans, isotope static brain scans, and contrast studies including angiography, pneumoencephalography, myelography, discography, and epidural venography.

It is obvious that not all or even a small number of patients presenting with a variety of subjective complaints of potential disease deserve any or portions of the above-mentioned studies. Many thoughtful physician observers would argue that the pursuit of a cause for subjective complaints in the absence of objective neurological or neurosensory findings is an expensive exercise in "diagnostic overkill." On the other hand, the relatively occasional but well known patient will have only a subjective complaint as headache and yet harbor a curable lesion, such as a patient with a meningioma.

It is often difficult to separate symptoms and the symptom complex of headache from cervical spine pain, but because headache is a most common complaint, I will describe the radiographic studies in its workup. I assume a detailed history, physical, and neurological exam have been done. This assumption, however, is primary and in our practice, comes only with personal association with our referring physicians. A radiologic exam, such as a skull series, is designed as a consultation in response to a referral of a patient with a problem and a specific symptom complex, but in another sense, we are screening for the presence of disease within the cranial cavity. Many of the x-ray procedures that I mention are often used in this sense, but do not meet the criteria that are necessary for a good screening exam. The efficacy of a negative exam is difficult or impossible to quantitate, but nevertheless, the importance of a negative test should not be underemphasized. We still see large numbers of "worried well" patients to whom negative studies yield immediate benefits. We recognize the social and economic impact of this, both positive and negative, and do not advocate liberal screening techniques using radiographic exams.

The first radiographic exam used for the patient with a headache has been a skull series, but I would raise the question now as to the wisdom of continuing this practice. A skull x-ray series has been traditionally used as the mainstay of admission diagnosis because it conveyed the opportunity for inspection of the cranial bony vault for disease and for secondary abnormalities such as thickening of bone, erosion of bone, or hyperostosis. It gave secondary information as to the presence or absence of a mass lesion within the skull which might displace normal calcified structures from the midline such as the pineal. And, finally, it might give secondary findings that would suggest chronic increased intracranial pressure secondary to a mass lesion within the skull. In 1936, Sussman reviewed 333 brain tumor suspects, and, of these, in this selected series of workup diagnosis, 156 harbored tumors of which 47 percent had primary or secondary findings on the plain films of the skull. This appears to be a relatively good yield, however, in actuality it represents an extremely low yield of positive diagnosis. This feeling has borne out over recent reviews. Thus, the plain skull film x-ray series has a relatively low yield of information and is only positive in low numbers even in a patient population that is highly suspect for intracranial disease.

What then is a more logical diagnositc technique in the patient suspected of intracranial disorder? The two examinations that quickly come to our mind are the radionuclide brain flow and brain scan and the computed tomographic study of the brain and cranium.

In the radionuclide study, we detect the actual flow of the isotope to the brain in a dynamic fashion, thus an assessment of the circulation to the brain is possible and the static brain scan allows study of the integrity of the linings of the brain, structure of the brain or the blood brain barrier. The exam risk is very low and the radiation exposure is similarly minimal.

Computed tomography, a relatively new technique, was designed and instituted into clinical practice in 1973 and has proven to be a remarkable quantum leap forward in neuroradiological diagnosis. The anatomy is faithfully reproduced and normal anatomy as well as pathological disease states are accurately delineated. The examination may be repeated following the injection of an iodine-containing contrast material which circulates within vascular structures which may be normal or abnormal, thus tumors or areas of stroke or abnormal vascularity may be accurately delineated.

What then is the relative contribution of radionuclide studies and/or computed tomography of the brain? Perhaps the most meaningful method of reviewing the contribution is to review the numbers of examinations that have been requested by physicians, because volume studies are in a sense a methodology for review of the physician's attitude toward contribution to diagnosis by these exams. A recent review of statistics in our department showed that since the advent of computed tomography, there has been a decrease in radionuclide isotope brain scan studies, a decrease in angiography and almost elimination of pneumoencephalography.

Computed tomography allows a much more efficient use of the health dollar which may prevent a need for hospital expansion because a significant number of patients no longer have to be admitted for radiological investigations. Estimates as to the accuracy of nuclear medicine studies and/or computed tomography vary, but it is generally accepted in the range of 80 to 90 percent. If both examinations are done, the accuracy can approach 100 percent. I certainly would not advocate the use of both of these studies in each patient but there are occasions in which the nuclide study can be helpful following a negative or confusing computerized tomogram.

Patients with typical tension headaches or uncomplicated migraine do not need any radiographic examinations. Patients with headaches of uncertain origin should have computed tomography to exclude an organic lesion and patients with a severe migraine or migraine with neurological sequelae should have computed tomography to exclude aneurysm or AV malformation and to evaluate the extent of migraine atrophy edema, or infarction. Patients with a headache and a subsequently normal CT are observed without further workup. A radionuclide scan can be of use in the diagnosis of an AV malformation or in small convexity meningiomas, and may also be of value when iodine allergy exisits preventing the use of contrast material in computed tomography. We concluded that CT should replace radionuclide scan and the skull series as initial diagnostic exam in patients with neurological abnormalities. Finally, the exception to the use of direct referral for CT instead of skull radiographic exams is in patients in whom pituitary lesions or other lesions in and about the sella or neural foramina are suspect.

In summary, the impact of radiological technique in the evaluation of symptom complexes is limited by the number of cases in whom false negatives and false positives occur. These limitations force a close critical cooperation between the referring physician and consulting radiologist.

An ideal test, which combines features of low cost, low morbidity, high sensitivity, high specificity, low false positives, and false negatives, does not exist in radiology today. The closest to the ideal in our opinion is a careful history, physical, and thoughtful physician examiner who uses consulting critically.

In closing, I would like to make some philosophical observations. The Bureau of Radiological Health, under the leadership of Mr. Villforth, has maintained a philosophy of working with and through the system. I hope you never lose this. The concept of John Gardner's partnership with Government is important. You must be vigilant in and maintain a variety of different output oriented initiatives, check for results all the time, changing as the available technological opportunity changes, resist the need for central policy. If central government says to us, "You cannot run efficient services but must use our failing ones," we shall object as citizens to this Public Sector Imperialism, and, as civilized people, tend to move outside of the control of central government. A monopoly in the hands of democratic government bureaucracy is no better than in the hands of corporations, kings, pharaohs, dictators, central committees, or marxist chairmen. Our system for 200 years has operated in an extraordinary number of overlapping governments at national and local levels who often prevent the other from doing very much. Government has ballooned because successive administrations have created new agencies or obsolete organizational units without allowing existing ones to die. As once stated, the egocentric battle among intelligent people for nonpower, immobilization through pluralization, and self-reversing trendiness cycle imply serious dilemmas for the future.

Thomas Kuhn in his treatise, "Structure of Scientific Revolutions," noted that scientists have turned to philosophical analysis as a device for unlocking the riddles of their fields. Revolutions are inaugurated by a growing sense, often restricted to a segment of the political community, "That existing institutions have ceased adequately to meet the problems posed by an environment they have, in part, created. Let us move into the future as Jonas Salk in a both/and concept rather than an either/or concept."

The radiologist should be responsible for quality in:

1. Medical consultation and imaging interpretation.
2. Quality control of imaging procedures under his direction.
3. Administrative and coordination of technologists.
4. Minimal radiation exposure doses to patients, staff, and public.
5. Economics - best images at lowest cost.
6. Expertise in technology and constant upgrading.
7. Continued self-evaluation and education.
8. Service to his community.

What shouldn't he do? Each of you have your own thoughts, predjudices, and experiences, and I leave this to you to decide.

WHY the PHYSICIAN NEEDS an X-RAY

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

My presentation, why the physician needs an x ray, reminds me of the quandry the x-ray receptionist found herself in, as usual, trying to decipher why that particular patient had appeared. Some physician had obviously felt he needed to have an x ray, or the information an x ray on the subject could provide, and simply told her to go to x ray and put this piece of paper in her hand with some illegible scribbling on it. The receptionist was looking it over, and finally asked the patient if she had been x-rayed there before, hoping to get some background information, maybe an old file. She thought about it a while, and she says, "No, I haven't been x-rayed here before but I have been ultraviolated here about 2 years ago." That is an old story, but the more the health care profession seemed to be ultraviolated the more significant it is. Also there is one of my favorite cartoons about the little boy that is in the physician's office and he is holding his arm up (I am sure you have seen it). In addition to the usual angles of the normal arm, here is a right angle in the middle of his forearm and the caption of the cartoon is the physician studies this in great detail is that, "Well, I think it is broken but we had better get an x ray to be sure!"

Obviously, the x ray provides information and, with the information, provides a host of other benefits to the physician and the patient and the patient's family, the patient's employer, the insurance underwriter, and a host of other anxious and wondering, interested persons.

Some of the reasons a physician needs an x ray are obvious. Some of the reasons are not obvious. And only a physician who finds himself challenged with the diagnosis, the need for a diagnosis, or the need to follow the progress of a known disease, can understand all of the ramifications of why he needs an x ray. Obviously, he needs to verify and obtain details of clinically apparent or suspected disease and/or disorders resulting from trauma. Those words, "clinically apparent" and "suspected disease," may at first seem to be similar but, I assure you, they are very different. Many patients that present the most challenging picture of symptoms and anatomical disturbances have the most serious disease and vice versa. It is the disease the physician may suspect, as well as the disease that is obviously apparent, that causes him to feel he needs an x ray. For example, if that arm belonged to a middle-aged man or a middle-aged woman instead of the little boy, and if that trauma had been almost negligible rather than a tumble off a skate board, the fracture just as obvious may be found after a radiographic examination to be due to an otherwise unsuspected disorder involving neoplastic disease, metastatic or primary cancer, or some bizarre, exotic, or rarely seen disorder of bone metabolism or protein metabolism.

Physicians obviously feel they need x rays in order to obtain information about the progress of disease and/or trauma-related derangements. It is one thing to make a diagnosis of acute pneumonia, one that can be done fairly expeditiously even without an x ray. It is another one to follow that patient to the point of complete disappearance of those abnormal findings, long since beyond the scope of physical examination, and be absolutely certain that the pneumonia was not the result of an obstructed windpipe, which caused an abnormal susceptibility to infection, and an otherwise unsuspected neoplasm or space occupying lesion.

The physician needs an x ray to reassure himself many times, so that he can, in turn, reassure the patient and/or the patient's family. If the worried well (a term that has been used many times and even here this afternoon) deserved anything in the hands of their physician, they deserve reassurance. And an honest physician can render that reassurance only if he himself has been reassured. So the need for an x ray might be titrated against the physician's need for reassurance and what it takes to satisfy him, and as well, what it takes to satisfy the patient who now reads every turn of the hands on the clock and hears on television why he should or why he should not have an x ray of the chest, an x ray of the back, an x ray of the kidneys, ad infinitum; which means, obviously, that physicians need x rays to satisfy a specific request of the patient and/or a member of the patient's family.

"But Mrs. Jones, I find no reason to take a chest x ray. I know that Mr. Jones smokes heavily and the chances of finding a significant disorder on the chest x ray so that it will mean something in the total absence of symptoms, really does not make much sense."

"I understand that doctor, but my brother just died of cancer of the lung and you know the doctor said he must have been carrying that around for 2 or 3 years and nobody knew."

Obviously, that spouse needs an x ray so that she can be reassured, and certainly the physician cannot reassure her faced with that statistical risk, that her spouse does not have a neoplasm of the pulmonary tree.

X rays are needed to fulfill a requirement specified in an examination order or request. Executive examinations, once more of a fad in the past than they are today, required certain minimum radiographic examinations, chest x rays, P/A, and lateral and lorodotic views, lumbosacral spine; even routine barium studies of the upper and lower gastrointestinal tract. A physician who accepts the obligation of performing this examination, accepts the obligation to requesting a consultation with the radiologist to perform these services and render an opinion. If he does not, he does not meet the minimum standards of the examination requirement and therefore he does not render to his patient the service for which the patient consulted him. Insurance examinations for life insurance, automobile insurance, home insurance, almost any kind of insurance might require a complete head to toe physical examination, and irrespective of findings, one or more radiographic examinations.

X rays are needed to obtain graphic evidence of the presence or absence of disease or traumatic derangement on a given date and time. In this need category, we find defensive practices. We can rationalize among ourselves, our other colleagues, our friends; we can agree; we can develop a consensus even that it is foolish to obtain this or that radiographic study. The chances of it showing anything significant, in the face of relatively negative findings on physical examination, are so remote that such a study almost constitutes neglect, if not technical assault. And yet what you and I know, what you and I understand, what you and I agree upon, may have, as a matter of fact rarely has, anything whatsoever to do with what a jury sitting in a malpractice suit decides is a just restitution of damages.

Obviously, x rays with dates and times and certain demonstrations are usually beyond equivocation and beyond challenge. They are the good physician's resource; his evidence. They are his defense. We can establish all the theoretical wisdom, we can embrace all of the prudent recommendations that come from any regulatory agency, any expert radiologic consultant or our own conscience, but none of them will help us when it comes time to produce a negative or a positive radiographic finding on a witness stand or in a court.

In my personal opinion, if the Federal bureaucracy really wanted to decrease the use of medical radiation, they could establish a moratorium on malpractice litigation. I have no way of knowing and I don't know of any of my colleagues that has a way of knowing how much this would reduce the irradiation exposure of the health care public, but I am sure it would be significant.

X rays are needed to allay criticism from a physician's colleagues as individuals, as consultants, or members of a hospital committee. I may know, or my colleague may know, full well that an x ray really is not going to be of any benefit. But when a consultant is called in, or when a friend of the family who happens to be a physician asks about the results of xyz x ray, the physician may have one ordered simply to respond to the question or to avoid criticism. He may know the case well enough, he may know the details of the history, he may know the details of the physical examination to the degree that he is almost certain that an x ray will provide no additional information, but be coerced in a silent way to obtain any number of x rays. Hospital committees and the more we see of protocol, cookbook therapy in hospitals, the more this is apt to happen. Hospital committees may say, well we have developed a consensus that it is prudent in cases such as this, with this diagnosis or in this age group or with these findings, to have xyz x-rayed, and they will be obtained.

X rays are needed to satisfy the suggestion of a consulting physician, whether it is formally or informally. Many times a consultant will see a patient or a colleague and, either not be able to find the detailed history and physical findings, or not have time to review them and thus suggest of such and such organ, such and such part be obtained in order to be certain that they are not dealing with a dissecting aneurism, and so forth.

X rays are needed by physicians to comply with actual or perceived screening programs. We have heard something about screening programs today. From what I am able to determine, from the consensus reports, very few screening programs are of significant value in many, many existing or anticipated disorders. Almost every strange procedure that is developed, with experience, and with the passage of time, with the accumulation of data and other statistical information, the screening program is either determined to be invaluable, of questionable significance, or actually harmful. But we physicians develop our own feeling about a need for screening procedures. Not many years ago, the experts in England were recommending chest x rays for heavy smokers over the age of 45 (I am told) every 6 months, at a time when American physicians felt that every 2 years was adequate. Now it appears, that it makes no difference whether it is 6 months, 1 year, every 2 years, or whatever interval, a retrospective evaluation of the patient who is known to have developed lung cancer may reveal that its presence could not have been detected by x rays had they been done every 6 months.

X rays are needed to obtain certain spatial and architectural information prior to a planned or anticipated event. The most common example, and it is rapidly being abandoned, which I think is healthful, is pelvimetry, to measure the pelvis to see if the expectant mother can actually deliver that child through the birth canal without anticipating or without having to establish a readiness for the performance of a Caesarian section. Today, the use and application of ultrasound techniques, I hope, will have made that procedure obsolete. I can foresee, and there have been in the past, there are currently, procedures primarily involving radiographic information of the skull that are necessary to measure certain relationships pending surgery on certain portions of the brain that may be in very remote or very difficult to ascertain places. This is primarily done in surgical procedures on the basal ganglia in the brain and most commonly in the effort to alleviate some of the ravages of Parkinsonism.

X rays are needed by the physician to expedite or compensate for deficincies in the elicited history and the physical examination performed. This may have been unavoidable; the patient may be unconscious; there may be no family there; the patient may be aphasic; the patient may be too old or too young to communicate or to understand, or the physician may not have had time or may not have taken time to elicit the details of a history and to perform a very complete and detailed physical examination, which might otherwise have indicated that that particular x ray was really not necessary. "How long have you had that crooked place in your back?" If there is no answer, there may be an x ray. If the answer is, "Oh I was born with that," there may not be an x ray.

And finally, I think, in some cases x rays are needed by physicians (and understand, this is my own view) to patronize a valuable medical facility so that its availability is assured.

We have heard that so many procedures are required in order to have the capability of doing computerized axial tomograms. I don't know what the figure is in a particular given case (but in some cases it is what--750?) in a certain period of time; 30 days, 60 days, 90 days, 6 months. Obviously, that is not a really valid reason to order an x ray or a radiographic study, unless it is the only possible way you can have the instrument and the personnel available to have them done when they are absolutely indispensible. The more demands, and the more requirements on a numerical basis, that any regulatory agency places upon the health care profession, before they are permitted to have access to these extremely valuable, pain saving, hospital bed saving, money saving, anguish saving, modalities, the more we are going to see the ordering of x rays or radiographic investigations based upon the need to have the facility available. The question is, will that legitimize what we feel as physicians we need from the radiologist and his resources.

REFERRAL CRITERIA--THE UNMET NEED to OPTIMIZE RADIATION USE

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(Presentation made by Dr. William S. Properzio, Director, Division of Training and Medical Applications.)

The subject of referral criteria for diagnostic x-ray procedures is not new to this audience. Discussions in a number of public forums over the past few years have focused on the need to develop rational guidelines for referring physicians. Such guidelines would provide some idea of the appropriateness of a particular x-ray procedure under a given set of clinical circumstances. In the midst of heightened public, professional, and Congressional concern about both radiation exposure and increasing medical costs, interest in referral criteria will probably not diminish in the near future. Obviously, radiology is not being singled out for special attention in this area, for it is not just the use of x-ray procedures that must be optimized. On the contrary, we are now witnessing widespread interest in the subject of cost/effectiveness in many areas of medicine, from surgery to length of hospital stays.

The extent of Congressional interest in x-ray referral criteria can be appreciated by the fact that a major national conference on the subject was requested and cosponsored this past year by a Congressional committee. The recommendations developed at the Conference will be summarized later. In his keynote address to the Conference, then Congressman Paul Rogers expressed the views of at least part of the Congress when he said "Our Subcommittee's three major concerns (are) increasing the quality of health care and reducing its cost, while eliminating unnecessary radiation exposure...we must develop x-ray referral criteria for use across the broad spectrum of medical and dental problems."

There is no need here to provide a detailed explanation once again of the various possible reasons for unproductive x-ray examinations. As we all know, the reasons include pressure from the patient, the use of x rays by the physician as a means of reassuring the patient, medicolegal considerations, and an understandable desire on the part of both the physician and the patient to "rule out" pathology even when the probability of finding an abnormality is extremely low. To this list can be added still another reason for non-useful x-ray examinations, namely a failure on the part of the referring physician to ask himself some hard questions as he considers requesting an x-ray procedure. Are the x-ray results, even if they are positive, going to make a difference in how the patient is managed? Is there an effective treatment for the disease I may find? Would a few minutes spent in counseling and reassuring the patient eliminate the need for this x-ray examination? Instead of an x-ray examination right now, would a "wait and see" approach be just as good? Rational referral criteria may eventually help to provide some answers to these basic questions, but in the final analysis, physicians must learn to ask the questions. And learning to ask them can be done now--it does not require the results of long-term studies or government sponsored panels or commissions.

How can referral criteria be established? One approach is to undertake efficacy studies which analyze the diagnostic effectiveness of x-ray examinations and their impact on patient management. Ideally, such studies can provide quantitative answers to three important questions. First, when a patient presents with a given combination of signs, symptoms and history, what is the probability that a specific x-ray examination (whether the results are positive or negative) will provide useful diagnostic information? And, what effect will this have on the way the patient is managed? Finally, to what extent will the patient's ultimate outcome be affected by the x-ray examination? Those questions are essentially what the American College of Radiology has called Efficacy I, II, and III. Like most things in life, this approach is easier to talk about than to accomplish. Studies which can give this information on a sound scientific basis are expensive, time consuming, and fraught with technical and statistical pitfalls.

An alternative approach which is attractive precisely because it is so much simpler, quicker and less expensive is to convene panels of experts drawn from radiology and appropriate medical specialties, and ask them to jointly develop suggested criteria based on their expertise and experience which can then be clinically tested. The potential problems here are obvious. Can the panelists develop a consensus? Are there enough areas in which they agree so that helpful criteria can be formulated? Do they represent a wide enough spectrum of approaches and opinions? Will their recommendations be credible? And so on.

Although we should have a realistic awareness of the pitfalls in using panels to develop referral criteria, we should not sell this approach short. Even if the panelists can come to an agreement only on what seems to them as the obvious indications and contraindications for a particular x-ray examination, this information may still prove helpful to those physicians in the "real world" who may not possess the special expertise of the panelists. What is obvious to an expert may be new (or long forgotten) information to a nonspecialist. In other words, stating (and explaining) the obvious in a clear, authoritative way may have a significant educational impact. To use an example outside the referral criteria area, all the experts know that good radiological practice dictates that the pregnancy status of a young woman should be ascertained when an abdominal x ray is being considered. Yet we all know that this "obvious" rule of good practice is often neglected, and so have found it necessary to develop specific guidance in this area. The same principle may hold true with respect to educating referring physicians about "obvious" issues concerning the indications or lack of indications for certain x-ray examinations.

Let us now proceed to a summary of what has happened in FDA over the past year with respect to referral criteria.

The major event was the National Conference on Referral Criteria for X-Ray Examinations which was cosponsored by HEW and the House Subcommittee on Health and the Environment. This meeting brought together the medical profession, government, third party carriers and the legal profession in order to discuss the need for referral criteria, perceptions of problems, and current referral criteria projects. The State radiation control programs were represented by its Efficacy Task Force. Four concurrent workshop sessions addressed the development of referral criteria, medicolegal aspects of the problem, patient needs, and administratively required x rays. The Conference proceedings, as well as a set of summary videotapes, are available from the Bureau of Radiological Health. The proceedings also include official comments submitted after the Conference by participating organizations.

Among the referral criteria issues considered by the Conference participants were the feasibility of using expert panels to develop criteria; the respective roles of the private sector and the government in these activities; the role of radiologist and other medical specialty groups in developing, testing, and implementing criteria; the importance of voluntary implementation; and mechanisms for disseminating criteria once they have been carefully validated.

Several key recommendations, which BRH is following, emanated from the Conference. First, the participants recommended that x-ray referral criteria should be developed and validated by the private sector. They supported the expert panel approach as one way to develop referral criteria and recommended that clinicians having expertise in the application of a particular x-ray procedure participate in the development of the criteria. The participants cautioned against reliance on a single set of criteria since such criteria may not be universally applicable. Before wide-scale implementation, criteria must be validated in a cross section of health care delivery settings such as urban and rural health centers, teaching and community hospitals, emergency rooms, clinics, and private offices.

The Conference participants believed that carefully validated referral criteria would not only lead to appropriate patient care, but might also serve to protect the physician in litigation. To that end, they recommended that medical societies assume an active role in acceptance and dissemination of referral criteria.

The government's role in the criteria development process was defined as that of a facilitator. The government, according to the Conference participants, should provide the funding necessary for assembling the panels, conducting research, collecting data, and aiding the dissemination effort. The participants further recommended that government hospitals be used as models to demonstrate the use of x-ray referral criteria.

Because of a need to adjust to changing medical practices, the participants recommended that x-ray referral criteria be established on a voluntary basis. However, the participants did believe that, once criteria had been validated, dissemination efforts could be strengthened by third party carriers. Therefore, they suggested that third party carriers support implementation efforts through the use of reimbursement policies and utilization review. A similar role was defined for hospitals. Here, workshop participants recommended that, in cooperation with local Professional Standards Review Organizations, hospitals implement medical care evaluation studies in diagnostic radiology.

In addition to the Conference, a major activity this year has been the management of three expert panels charged with developing referral criteria for (1) the pelvimetry x-ray examination, (2) voiding cystourethography in pediatrics and (3) chest x rays. Each of these panels has met at least once. The pelvimetry panel, composed of representatives from the American College of Radiology and the American College of Obstetrics and Gynecology (ACOG) has developed a policy statement concerning the use of that examination. At this time, final wording of the statement is being reviewed by ACOG.

The Chest X-Ray Panel has met once this year. It has very broad representation. Because the States have a significant role concerning requirements for administrative chest x rays, Jerry Parker has been asked to serve on that panel. The recent survey of administrative x-ray requirements which Jerry sent to the States was made available to the panel at its recent meeting. Additional data requirements have been identified by the panel, and these data will be collected prior to their next meeting in the early fall. The anticipated information includes frequencies and requirements for various categories of chest x-ray examinations, a demographic breakdown of known active tuberculosis cases and a determination of the distribution of reasons for ordering chest x rays.

Another activity used on the collection of data concerns the utility of routine hospital chest x-ray examinations. These examinations include hospital admission and pre-surgical x rays. We began this activity to answer a number of questions. For example, the extent of routine use of these examinations is not known. Through a contract we are sampling 10 percent of U.S. hospitals to determine their policies on hospital admission and pre-surgical chest x-ray examinations. In addition, data from nine New England hospitals are being collected and analyzed. These data include information on the reason for the examination, patient demographic information, and examination yield. The information from the contract will be made available to the Chest X-Ray Panel for its consideration.

As noted earlier, there are various methods to develop referral criteria. A second approach we wish to pursue involves local clinical studies. In early March, the Bureau issued a request for grant applications directed at developing criteria for specific x-ray examinations. The objective of the grant solicitation is to encourage research that will evaluate selected diagnostic radiological procedures in terms of clinical productivity and contribution to patient care. The end point of the studies would be referral criteria or algorithms for specific x-ray procedures. So far, over 40 letters of intent have been received. Grants are expected to be awarded at the end of this fiscal year and during the next fiscal year.

We all recognize that development and implementation of x-ray referral criteria is a very complex problem. So far we are encouraged by the progress made by the criteria development panels, by the letters of endorsement from professional organizations, and by the research interests of the medical community.

I know that there has been skepticism on our part as well as that of the medical community about cooperative government/medical profession efforts to reduce unnecessary x-ray examinations. We believe that atmosphere is changing. Here are excerpts from two of the many letters we have received subsequent to the Conference. From the American Academy of Family Physicians, "The American Academy of Family Physicians is interested in cooperating with other medical organizations and the government in developing voluntary guidelines for x-ray referral criteria...the Academy will help disseminate validated referral criteria through appropriate publication after they have been developed and validated." From the American College of Radiology, "In reviewing the reports of the workshops, we find most of the initiative to be commendable in respect to objectives which the (American College of Radiology) and the Bureau have shared for some time....It is still too early to determine the lasting impact of the Conference and the ideas it generated. We strongly endorse the repeated statements in the concluding session that it is worthwhile for all of us involved in medical radiation to continue the dialogues, the interests, the arguments and the projects which were stimulated in those sessions."

We think that these statements, as well as the many encouraging remarks we have heard from individual physicians, characterize a growing understanding of the problem of x-ray overutilization, and a growing willingness to work together to solve it. Referral criteria can become an effective tool, if properly developed and validated, in the overall effort to reduce unnecessary radiation exposure and medical costs.

THIRD-PARTY ROLE in REFERRAL CRITERIA

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader).

It is interesting that in my role (I have been in administrative medicine over 10 years now), my progress or maturity, if you will, in the administrative medical arena is analogous to a young lady as she progresses in life. The early years of my administrative medicine was much like the young lady of 20 who blushed when a man praised her. You know, whenever I got praise from someone in clinical practice, I practically blushed, and I was happy about it and this sort of thing. But a young lady of 30 thinks the fellow is quite clever whenever he says this. As I matured, I felt I was coming right along when one day someone in clinical practice told me I was maturing. And I find that as the young lady moves into 40, when she is praised, she wonders what he wants. Those of us in the third-party arena I am afraid sometimes become a little paranoid in communication and we wonder how many things we can do to increase favor and that sort of thing as the inquiries come to us.

My talk today is going to be like the difference between gossip and news; it depends on whether you want to hear it or tell it. I hope that what I have to say will be what you want to hear and not what you would like to say in this area of referral criteria in the third-party arena. Let me set the record straight right now. Referral criteria in the third party arena does not totally relate to what you have heard thus far about referral criteria. Referral criteria in the clinical sense, is more diagnostic and more procedure related, in a clinical qualitative assessment way. In the third party arena, we are more qualitative in our approach to evaluating our criteria as it relates to radiological procedures. For many years, we felt in the third party arena, that the quality of care, if you will relate that to ionizing radiation exposure, has been a matter for peer review and for the medical profession to evaluate its own; and the quality assessment lies in that arena. I still feel a great deal of that responsibility falls in that arena; however, as I progress in this area of utilization review in the third party arena, I identify data that are available in the third party arena that may or may not be available to you in the practicing arena.

I know that over the years, third party clinical practitioners have looked upon those of us in the third party arena with black hats on. That is, we are always coming back and finding out how to cut the payments, how not to pay for something, and this has negatively impacted our relationship in some areas. I would say to you at this time, that those of us in third party medicine, I think, are coming around to the idea that that approach to a relationship with organized medicine is not the most beneficial approach. It does not promote the best care for either those members of our plans in the private arena, whether it be Blue Shield, whether it be Aetna Travelers, or Prudential, or whatever else. In the Federal program, this does not make for good relationships between the physician, the patient, and those of us in third party. I think we are coming around to identifying areas that we might increase our input to organized medicine to assist in the quality assessment of health care with the data that might be available to us.

I will expand on that further in my presentation, but first I would like to say that surely our role in utilization review has primarily been aimed toward the potential fraud that you keep hearing about, the potential abuse that you keep hearing about; the potential over-utilization of procedures. Indeed, the referral criteria from my viewpoint, may well be looked upon as self-referral, or consultative-referral, rather than referral criteria by diagnosis of procedure. that is one of the problems that we face in third-party medicine in evaluating in the radiology area or even in the laboratory area; self-referral. We relate not only to radiologists with regards to radiological procedures, but to internists, family practitioners, and indeed anyone that has a practice, or license, if you will, to practice medicine. We are obligated to make payments to them for whatever procedures they perform so long as it is within the realm of "nonexperimental accepted medicine" in the community in which they practice. Our role in identifying a claim for a service when it comes into us, is to identify whether or not that claim is appropriate for payment. In receiving anywhere from 13,000 to 20,000 claims a day, a large percent of those would be for radiological procedures. In receiving that many claims a day, it is difficult to assess each claim as it comes through.

What we attempt to do in the third party arena, is to identify for postpayment review, physicians by specialty and by geographical region, so that when we identify a pattern or a trend, we do it by specialty. We identify those family practitioners, we identify the internists with internists, we identify the radiologists with radiologists. The one area where you may get a free ride, if you accept it as a free ride, is that when that claim comes in from radiologists, we do not require a diagnosis to be affixed to it. In many cases we do request it from the referring physician, because what we like to identify are those physicians that order a large number of procedures through others, so that we can then through our sophisticated claims processing, postpayment utilization review capabilities, identify those physicians that might be abusing the program by referring patients that may not need these procedures. Indeed, although a small percent, we have identified many physicians in the primary practice of obesity evaluation, that refer a large number of patients for radiological procedures that are not totally medically necessary for the condition for which they are being treated or evaluated.

In the claims processing system, we do have a prepayment basis. What that means is, when you send a claim in, some of us have the capability to identify and evaluate that claim prior to making a payment, and in this case we do have, in our jargon, what we call prepayment parameters or screens. This would relate somewhat to referral criteria in the clinical sense, because what we have identified are those procedures that would relate to a human diagnosis. The problem that we have is that in the hospital arena, when we receive a claim for certain services, we have the diagnosis, we have all the surgical procedures which they receive, but what we do not have is a specific listing on the claim form of all the individual radiological procedures performed, or laboratory procedures for that matter. These all fall under the area called ancillary service review. I am involved in a National Task Force in an attempt to identify methods and methodologies whereby we might correct that problem and more closely identify a possible overutilization, if you will, in the hospital arena, of unnecessary laboratory or x-ray studies.

The problem I have when I make some of these statements to a group like you today, is that you are probably not the ones that have the problems. The problems are generated, if you will, by the 5 percent or 7 percent of practitioners that do abuse, do overutilize, may be on the grey zone, in the quality of care they provide to their patients. This is not meant to be a derogatory, adversarial approach to the health care system in America today. It is just an objective assessment, from my 10 years of practice from looking at claims from all sorts of physicians, that the small number of physicians is what causes our headaches today. I can assure you that the volume of problems that that small percent generate is significant.

Those of you in hospital practice may wonder what I am really talking about. In one State we have over 60 hospitals. The majority of those hospitals are under 50 beds. Many of those under 50 beds are small hospitals owned and operated by physicians. This is not bad in and of itself. It is just that when you find that, normatively, we find a larger number of x rays being provided in those institutions per patient than we do in some of our 1000-bed community hospitals or teaching centers; then we may have a problem. I am not saying that we do have a problem; I am saying that statistically, it is something that needs to be looked at. This is the sort of data that third parties have and I would hope that you would develop or have a relationship with your third parties that you could get them to share with you that data, so that you might assist them and assist your peers in better evaluating the quality of radiological services provided in your State, either by your peers or by your family practitioners or general practitioners or internists or the specialties that primarily do x rays--but it all falls into the basket of quality assessments.

I represent Electronic Data Systems Federal today, and their subsidiary National Heritage Insurance Company, which manages the Medicaid program in Texas. We have some 10 other States that we either administer as the fiscal agent or administer with State agencies, the Medicaid programs. Many of you are aware that recently we were awarded the Part B contract in Illinois and with regards to making claims payments. So I bring to you a large amount of experience in dealing with physicians in quality care from different States. With regards to claim payment, let me just very quickly say that in Illinois, like in some other States, when you first start off you have some problems with regards to payments and some of those problems relate to the type of criteria prepaid parameters that you develop. I am happy to say that we have resolved many of those problems in Illinois.

In the claims processing, we go through and apply our parameters on a prepayment basis. I have indicated primary qualitative, we look at the cost per case, per stay in the hospital and those that exceed a certain amount we go back and get the additional information and then do an evaluation. You see, our problem in many cases, is not the radiologist, not the internist, but it is the attending physician, because many of you know that in the hospital setting and indeed in many of your private standing offices, your patients are referred to you in a consultative way, and we do not primarily have a problem with. What we do have a problem with is the source of the referrals, and this is where we will be developing a greater input, a better criteria of evaluating and working.

Now let me quickly add that the philosophy I bring to Electronic Data Systems Federal in this arena in the past would have been to identify those referrals and immediately cut off the payments to you for those services from that referring physician. That is the black hat approach. I was at the University of Texas, Galveston visiting with a psychiatrist and I was talking to him about some of the regulations that we have that we all know are onerous. I was happy to talk to him about them and he said, "Fred, you just pulled a word out of the air and you are going to have to paint it green before I understand what you are talking about." I had a quick thought and I said, "Okay, you are going to bill me for all the overuse of these services by psychiatrists and at the end of a certain period of time I am going to come back and we are going to sit down and I am going to say: 'Dr. Jones, I now have to have $60,000 back.'" He looked at me and said, "Fred, you just painted it green. I understand what those regulations are all about."

The new concept that we are working toward, and I hope that this would indicate a closer relationship with the private practicing community, is more of an educational approach. Instead of cutting off, we now are going to take the data that we have, and our first cut is going to be to go out and visit with the referring physician or the physician that has self-referral. We are going to visit with him, we may even come to visit radiology offices, private offices. We may come to the radiology areas in hospital center and visit with you to develop as much of an understanding as possible. Then based on what we find, when we visit with the referring physician, we will implement prepayment criteria that may reduce payments in those areas--but in an educational sense, in a cooperative fashion, so that you have a better understanding of what we are doing. The referring physician will have a better understanding, and then if education does not take place, then the end result is painting it green and working with you in trying to reduce those problems.

Let me ask you this: In your given hospital, you have records on the patients in that hospital, you have records on the patients that come to your offices; do you know historically, what exposure they have had at your institution? But do you know that in the Medicare and Medicaid programs and indeed in many of the private, regular business programs, we have a lot of doctor-hopping-around. In the third-party arena, we have the data about the total number of procedures that any given individual has had. My interest in ionizing radiation has been ongoing now for several weeks, and I have to tell you before I share this data with you that it is raw data and I hope you accept it as that because I have not had a chance to really massage it. It is just meant as a naked sharing with you of three cases. There are many others. What I did was to screen some of the histories and some of the patients in one of our large Medicaid programs to identify some patients with the number of x ray procedures they had in a given period of time; in this case, some 18 months. I have included some lab studies.

One case is a 28-year-old female. I just sketched the history and found that she has not had a historectomy, she still has her ovaries and in an 18-month period, these are the procedures she received: A lumbosacral spine series (more than five views); a chest and P/A lateral; a lumbosacral spine series repeated; a thoracic spine series; a KUB; a chest P/A lateral; a barium enema; an IVP; an upper G.I. series; a liver scan; an abdomen, one view; an ankle x ray; another IVP in another hospital; an echogram (she had 4 echograms for a diagnosis of possible pregnancy after all this irradiation); another chest P/A lateral; another KUB; another chest; and then at another hospital she had a repeat P/A lateral of the chest; an abdomen, two views; a repeat abdomen, 2 views; again a KUB; again an abdomen, two views; chest, one view; a repeat KUB; another KUB; and then nine more abdomenal x rays of 2 or 3 views each in a 12-day period; a repeat KUB; another abdomen; another chest, 2 views; another KUB, another upper G.I.; another abdomen; another KUB; 2 more chests; 2 more KUB's; another chest; 2 more abdomens; and finally 2 more abdomens, 2 more views. Based on that individual, in an 18-month period, recognizing all the disparities between skin dosage, gonadal dosage received in the terminology (it is obvious that I am an obstetrician, gynecologist, not a radiologist) that you all know so well and are so familiar with, whether it is rad, milliroentgens or what have you, my people pulled together for a real quick survey, these procedures and a number of milliroentgens per procedure, and what we came up with was 49,204 milliroentgens of skin entrance in an 18-month period. I have not researched this enough to know whether that is that bad or not, but to me in my niave state, it appears to be awfully bad. In two other cases, we have a 28-year-old female and a 35-year-old female and the total milliroentgens in each case was 24,690 and the third one was 23,486.

Now recognizing that those figures (you know we may have missed a little here, we may not have added enough here and that sort of thing), I think that the point I really want to make to you, is that some of us in the third-party arena, stand ready and are attempting to develop the type of data that will assist you in developing your referral criteria. I think that if physician on physician, we can sit down together in a cooperative attitude, it is amazing what I think we can work out in assistance from the third-party arena, clinical practice arena, and come together in assisting in this area of quality assessment and quality assurance. This information, I think is just the tip of the iceberg to what we might have if we could relate with you. I think we should all look forward to working together and coming up with a better product for our patients.

STATE ROLE in BETTER UTILIZATION of X-RAY TECHNOLOGY

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The 1978 goal of the Efficacy Task Force was to determine what role the States should play in the better utilization of x-ray technology. In general, it was the consensus of the Task Force that the State role should remain primarily educational, rather than regulatory in nature. At the same time, however, there is a recognized need to abolish or amend existing regulations that mandate the use of low yield x-ray exams (for example, chest x rays for mass screening purposes). Four main areas of possible involvement have been determined.

1. Defensive Radiology
2. Administrative X Rays
3. Physician Education
4. Development of X-Ray Referral Criteria

There are differing views as to how large a role defensive radiology plays in increased exposure to the general public. A need thus exists for studies to be done, specifically concerning the role of x-ray evidence in the outcome of malpractice suits. Such studies could be conducted by the States with coordination at a national level. It has also been suggested that States could perhaps develop "no-fault" insurance programs to help protect physicians against malpractice suits. Caution must be exercised in this area, however, so as not to infringe on a person's constitutional right to bring suit.

The second area for State involvement is that of administrative x rays. Examples of administrative x rays include preemployment exams, hospital admission chest x rays, and mass screening x rays. In other words, we have classified administrative x rays as those exams that are performed on asymptomatic individuals without prior physician evaluation on an individual basis.

Despite a 1972 Chest X-Ray Screening Policy statement endorsed by the American College of Radiology, the American College of Chest Physicians, the Bureau of Radiological Health, FDA, and the National Tuberculosis and Respiratory Disease Association, governmental regulations still exist that require chest x rays for tuberculosis screening purposes. Even when laws have been changed to allow for skin tests, many organizations persist in requiring employees to obtain chest x rays because, as the old saying goes, "Old habits die hard." Where regulations do not exist, public pressure equating chest x rays with "good" medical care has led to the continued popularity of x-ray exams being included in multiphasic screening programs. More recent regulations also exist that use chest x rays as screening procedures to detect pulmonary disease for persons working in hazardous industries such as asbestos plants and coal mines.

The magnitude of this problem was not fully realized by the Pennsylvania Bureau of Radiation Protection until a few public complaints in 1974 led to an investigation into the matter of administrative x rays. Results of this survey showed that 20 of the 25 local tuberculosis associations, as well as two city health departments, were still conducting mass x-ray screening programs. Twenty-one of these were using photofluorographic equipment. Most school districts, although not required to do so legally, were still using x rays to screen for tuberculosis because the teachers refused to have skin tests for fear that the skin test would be positive. At that time, one school district required chest x rays for all students participating in sports, while another was x raying all eleventh graders. This situation in Pennsylvania has improved since the passage of our mass x-ray screening regulation, which requires individual physician prescriptions or prior approval of the screening programs by the Bureau in consultation with the Secretary of Health. However, it is well to remember that "when there's a will there's a way" and some mass x-ray screening still takes place in Pennsylvania since there are physicians still willing to provide "prescription" services.

Other classifications of administrative x rays include those that some employers require or offer to their employees as part of comprehensive health programs (for example, preemployment and periodic chest and/or spinal x rays). Some third-party carriers require x rays as proof of injury for treatment. Some medical facilities require admission chest x rays on all patients, while others require them only for surgical admissions.

States should make an effort to find and reevaluate existing or proposed regulations requiring the use of x rays for screening purposes. Medical facilities, industries, third-party carriers, and other groups should be encouraged to make cost/benefit analyses with regard to their administrative x-ray programs. Again, however, guidance as to the justification for administrative x-ray programs must be obtained from the medical community and programs should not be discontinued because of government judgment alone.

Programs should be developed and presented to the general public by the States with regard to both the benefits and risks of x-ray exposures. The fact that a "chest x ray a year" does not, necessarily, keep the doctor away should be stressed. As public awareness with regard to radiation safety increases, the use of administrative x rays should decrease proportionately.

A third area for State involvement would be to determine the educational activities of medical schools. There are currently 116 medical schools in the United States that the Efficacy Task Force plans to contact this year to determine how many require their students to take radiation related courses for internships. It is felt that few schools require participation of students in formal radiation courses at this time, although 52 schools do have the Diagnostic Radiological Health Sciences Learning Laboratory available for student use. This Learning Laboratory is designed to teach physicians how to select the patient for an examination, how to conduct the examination, and how to interpret the results. A community effort may be needed between the States, the American Association of Physicists in Medicine, and the American College of Radiology to promote use of this Learning Laboratory or other appropriate courses by the medical schools in the form of required courses for all students. Continuing education courses in radiation protection should also be developed for presentation to practicing nonradiology physicians. In addition, programs to promote increased communication between radiologists and other physicians should be encouraged.

A fourth area warranting attention is that of x-ray referral criteria. Although most States probably cannot supply financial assistance, we can offer manpower for data collection and for dissemination of clinically validated referral criteria. It is important that use of referral criteria be established on a voluntary rather than regulatory basis to allow for flexibility as medical technology changes. As previously stated, close cooperation between government and the medical community is necessary if any programs aimed at better utilization of x-ray technology are to succeed.

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CONCURRENT SESSION A: ULTRASOUND - "THE STATE-OF-THE-ART"

Moderator: *David K. Lacker*, Texas

WHAT DO WE KNOW ABOUT THE BIOEFFECTS?
Melvin L. Stratmeyer, Division of Bioeffects, Bureau of Radiological Health, FDA

ULTRASOUND DIAGNOSTIC EQUIPMENT AND ITS USE
Ross E. Brown, Department of Radiology, University of Oklahoma

ULTRASOUND POTENTIAL AND NEW APPLICATIONS IN MEDICINE
Marc S. Lapayowker, Professor and Director of Diagnostic Radiology and Chairman of the Commission on Ultrasound, American College of Radiology

DIAGNOSTIC ULTRASOUND OUTPUT LEVELS AND QUALITY ASSURANCE MEASUREMENT TECHNIQUES
Harold F. Stewart, Division of Electronic Products, Bureau of Radiological Health, FDA

THE BRH PROPOSED ACTION PROGRAM FOR DIAGNOSTIC ULTRASOUND EQUIPMENT
Robert G. Britain, Director, Division of Compliance, Bureau of Radiological Health, FDA

CONCURRENT SESSION B-1: WASTE MANAGEMENT

Moderator: *E. Frank Wilson*, Arkansas

THE ADMINISTRATION'S PLAN FOR RADIOACTIVE WASTE MANAGEMENT
Goetz K.H. Oertel, Director, Division of Waste Products, Department of Energy

STATE RESPONSE TO THE FEDERAL PROGRAM FOR RADIOACTIVE WASTE MANAGEMENT
Charles M. Hardin, Manager, Radiation Control Branch, Kentucky Department for Human Resources

CONCURRENT SESSION B-2: TRANSPORTATION OF RADIOACTIVE MATERIALS

Moderator: *J. Dale McHard*, Oklahoma

PANEL ON STATE NOTIFICATION
E. Frank Wilson, Director, Bureau of Environmental Services, Arkansas Department of Health
Aubrey Godwin, Director, Division of Radiological Health, Alabama Department of Public Health

FEDERAL-STATE RELATIONS IN THE TRANSPORTATION OF RADIOACTIVE MATERIALS
Lee Santman, Materials Transportation Bureau, Research and Special Programs Administration, DOT

STATE SURVEILLANCE OF RADIOACTIVE MATERIAL IN TRANSPORT - GEORGIA
Andrejs Simanis, Chief, Radioactive Materials Control Section, Radiological Health Unit, Georgia Department of Human Resources

GAO REPORT ON THE TRANSPORTATION OF RADIOACTIVE MATERIALS
Michael Gryszkowiec, Assistant Director, Energy and Minerals Division, U.S. General Accounting Office

WHAT do we KNOW ABOUT the BIOEFFECTS?

Melvin L. Stratmeyer, Ph.D.
Division of Bioeffects
Bureau of Radiological Health, FDA

In the last decade ultrasound has developed and matured from a laboratory and clinical curiosity to a diagnostic tool that is widely accepted, widely used, and considered essential to good patient care by physicians.

The extent to which diagnostic ultrasound is currently used has not been precisely quantified. A survey of all medical uses of ultrasound in short term general hospitals, conducted by the Bureau of Radiological Health in 1971, found that it was used in 12 percent of U.S. hospitals. The Bureau of Radiological Health has conducted a more extensive survey that examines the use of ultrasound during pregnancy, evaluates the extent of use, the trimester of exposure, and the stated indications for use. Preliminary data from this survey indicate that in 1974 approximately 16 percent of the obstetric services in the United States had diagnostic ultrasound equipment available and that about 1/3 of the live births in the United States in 1974 were delivered in these hospitals (1). Thus, diagnostic ultrasound facilities have become increasingly available, creating the potential for widespread exposure of the U.S. population to this diagnostic modality.

The development and increased use of diagnostic ultrasound has stimulated research designed to evaluate the potential risk or safety that may be associated with ultrasound exposure. One of the arguments for safety is the apparent absence of reported adverse effects associated with the diagnostic use of ultrasound. The absence of such effects has some value, but it does not permit the conclusion that ultrasound is safe, for the existence of subtle and delayed effects has not been carefully evaluated in well designed systematic epidemiologic investigations. A balanced approach to the scientific determination of risk associated with exposure would require the conduct and evaluation of both experimental and epidemiological research designed to test and probe the existence of risk.

We have previously reviewed human studies that have attempted to examine effects of ultrasound exposure on the fetus in utero (2,3). The largest study was conducted by Hellman, Duffies, and Donald in Great Britain, Sweden, and the United States. In this study, ultrasound examinations were carried out on 1,114 apparently normal pregnancies. This study evaluated the outcome of pregnancy and the number of infant abnormalities in the exposed population. There was no control population. The frequency of infant abnormalities observed in this study was 2.7 percent. The author stated:

> "These patients are not representative of a population of pregnant women since they were selected to conform with the objectives of specific ultrasonic studies and not to test the safety of the method. Thus we cannot validly compare these data with the incidence of abnormality in the general population. It is interesting, however, that the frequency of fetal abnormality in a large survey involving twenty-six hospitals and 63,238 single births in the United States was 4.8 percent, which is a much larger frequency than was observed in this study. Although our findings do not prove conclusively the safety of diagnostic ultrasound examination, we can say that neither the frequency of ultrasound examination nor the time of the first examination seems to affect adversely the incidence of fetal abnormality and abortion; nor are abnormalities any more common than in the general population" (4).

However, with followup limited to the newborn period, no inferences can be made regarding possible delayed effects. Even the lack of anatomic abnormalities is not particularly reassuring. Anatomic abnormalities obvious at neonatal examination would be expected to result from insult during the period of major organogenesis, however, the majority of the exposures in this study occurred well after this period had passed (3).

A study by Bernstein involved 720 patients (5). Two groups were followed and their experience was combined. The first group had no complication during pregnancy. The second group consisted of patients who suffered medical or obstetric complication during pregnancy and required hospitalization. No matched controls were included in this study. The incidence of prematurity and congenital anomalies in the study group was half of the U.S. Navy statistics on prematurity and anomalies. "This comparison, though tempting, is also tenuous because the data collection and the characteristics of the study sample are not described, and the populations may have been quite different. The apparent benefit associated with ultrasound was not explained and suggests differences between the groups which preclude simple comparison" (3).

Because of the limitations of past human studies that have attempted to examine effects of ultrasound exposure on the fetus, we believe no conclusive statement can be made as to the safety or risk on the basis of epidemiological investigation. Let us now examine the available information derived from experimental animal studies for evidence of risk associated with exposure to ultrasound. These data have previously been summarized in a Symposium held at the Bureau of Radiological Heath (6).

Much of the early experimental animal work in ultrasound bioeffects has limited applicability for assessing the potential risk from medical ultrasound applications. Many of the early studies used intensities that were well above diagnostic intensities and examined endpoints that often were representative of only gross pathological damage. However, recent literature tends to illustrate that as more sensitive endpoints are studied, the intensity levels at which effects are being detected is decreasing. Arguments can be made that many of the studies do not represent the exact exposure conditions of the clinical situation; or that the dosimetry is inadequate; or that the data have not been verified by other investigators; or that most of the data involve continuous wave exposure. However, from a public health point of view not all such studies can be dismissed as irrelevant, particularly since some of the studies involve the use of clinical devices.

DEVELOPMENTAL EFFECTS

Of particular concern are those studies that indicate that ultrasound can affect the development of laboratory animals exposed in utero, especially considering the extent of use of ultrasound devices during pregnancy and the recognized susceptibility of embryonic tissue to a variety of insults. Table 1 illustrates some of the developmental effects that have been reported thus far.

Table 1. Developmental effects of ultrasound

Average[1] intensity mW/cm^2	Total exposure time, min	Test system	Effect observed
10(cw)[2]	5	Rat	Delayed neuromuscular development (7)
20(cw)	300	Rat	Delayed neuromotor reflex development (8)
20(cw)	300	Rat	Altered emotional behavior (9)
40(cw)	300	Mouse	Fetal abnormalities (10)
125(cw)	3	Mouse	Postpartum mortality (11)
500-5,000(cw)	0.17-3	Mouse	Reduced fetal weight (12)

[1] Spatial and temporal average

[2] Continuous wave ultrasound

It should be pointed out that clinical diagnostic devices were used for the exposures in the studies reporting delayed neuromotor reflex development (8), altered emotional behavior (9), and fetal abnormalities (10).

HEMATOLOGICAL AND VASCULAR EFFECTS

Several studies have reported demonstrating that ultrasound can produce in vitro and in vivo hematological and vascular alterations (Table 2).

Table 2. Hematological and vascular effects of ultrasound

Average[1] intensity mW/cm^2	Total exposure time, min	Test system	Effect observed
50(cw)[2]	1.5	Rabbit eye	Vascular changes (13)
65(cw)	5	Human blood	Decreased in vitro clotting time (14)
500(cw)	2	Canine bone	Hemorrhage (15)
500(cw)	> 0.1	Chick embryo	Blood stasis (16)

[1] Spatial and temporal average
[2] Continuous wave ultrasound

Considering the wide use of ultrasound in cardiovascular diagnosis and in therapy applications, the possibility that such effects could represent a health hazard to individuals already predisposed to abnormal hematological or vascular conditions must be more thoroughly investigated.

NEUROLOGICAL AND BEHAVIORAL EFFECTS

Some of the more sensitive indicators of ultrasound-induced alterations, from an examination of the current litarature, appear to be associated with the central nervous system. Table 3 indicates some of the neurological and behavioral effects (including some mentioned in the Developmental Effects section) reported at diagnostic intensities.

Table 3. Neurological and behavioral effects of ultrasound

Average[1] intensity mW/cm^2	Total exposure time, min	Test system	Effect observed
1.5(P)[2]	360	Canine CNS	Increased GOT levels in cerebrospinal fluid (17)
3(P)	*	Primate CNS	Altered EEG response (18)
10(cw)[3]	5	Rat	Delayed neuromotor reflex development (7)
20(cw)	300	Rat	Delayed neuromotor reflex development (8)
20(cw)	300	Rat	Altered emotional behavior (9)

[1] Spatial and temporal average
[2] Pulsed ultrasound
[3] Continuous wave ultrasound
*Evoked E.E.G. responses appeared immediately upon start of sonication but disappeared after 3 minutes exposure.

All of the studies, with the exception of (7), used diagnostic instruments for exposing the experimental subjects. Furthermore, it is of interest to note that the studies involve functional, as opposed to anatomical, lesions as a measurable endpoint.

GENETIC EFFECTS

The long-range implications of genetic alterations, either somatic or heritable, are so serious that the possibility of genetic effects must be exhaustively investigated. Table 4 lists some of the studies that indicate interaction of megahertz ultrasound with genetic material.

Table 4. Genetic effects of ultrasound

Average[1] intensity mW/cm^2	Total exposure time, min	Test system	Effect observed
4(P)[2]	10	Hela cells	Decreased incorporation of nucleic acid precursors (19)
200(cw)[3]	1	Vicia root	Chromosomal aberrations (20)
200(cw)	15	Calf thymus	DNA strand degradation (21)
400(cw)	3	Calf thymus and salmon sperm DNA	DNA strand degradation (22)

[1] Spatial and temporal average
[2] Pulsed ultrasound
[3] Continuous wave ultrasound

Many of the effects of ultrasound on genetic material have been discounted by some investigators because of peculiarities of the test systems. One of the principal arguments is that the studies were performed under conditions in which cavitation could occur, and cavitation has not been demonstrated to occur in mammalian tissues at the intensities employed in these studies. Even if this argument is accepted, the recent report of altered incorporation of nucleic acid precursor into HeLa cells irradiated with a clinical pulse-echo device, under conditions presumed by some investigators not to be conducive to cavitation, requires further investigation.

It is encouraging that the studies on heritable genetic alterations induced by ultrasound have yielded negative reports to date, including a recent study in mice (23). However, it is disconcerting that few mammalian systems have been tested. Even the recent mouse study (23) shows considerable variability of the data in some of the tests performed and was conducted with rather small sample sizes (24). Again, the current data on the genetic effects of ultrasound are inconclusive. Indeed, it can be stated generally that the data on many of the effects of ultrasound are, at best, inconclusive. Until more information is available on such effects, a definitive assessment of the potential risk will not be possible.

We have an obligation to explore and define the degree of risk that may be associated with human exposure to ultrasound. It is essential that we have this information, that we may better be able to place this diagnostic tool in proper perspective. Should there be negligible risk, and should factors of safety be adequate at diagnostic levels, then we might adopt a justified attitude of non-concern over diagnostic exposure--at least as far as health implications are concerned. Should there be substantial degree of risk associated with diagnostic ultrasound exposure, this might justify a more conservative approach to the use of diagnostic ultrasound. This is not unlike the situation that holds for another diagnostic modality whose value is recognized and whose risk is better defined; i.e., the medical x-ray. Thus, where medical x rays are concerned, the need to weigh benefit versus risk is recognized. There is a recognized justification for the judicious use of x rays; i.e., wherever a diagnostic benefit is necessary that justifies the risk of the diagnostic procedure, the diagnostic procedure should be performed.

The existence or potential existence of risk is not the only motivation to regulation. Responsible voices have urged serious consideration of approaches to regulation that would improve the reliability and reproducibility of diagnostic instrumentation. Such regulation could provide, through effective and selective labeling requirements, information that would be useful to the user of diagnostic ultrasound instrumentation. Such requirements could improve reliability and uniformity of instrumentation and make it a more effective tool in the hands of the physician. This in turn might pave the way for increased efficacy--which we might define as a greater yield of information per unit of patient exposure to ultrasound.

There is still another justification for the careful evaluation of the degree of risk associated with ultrasound exposure. This new diagnostic modality could potentially provide an alternative of greater flexibility and lesser risk than the medical x ray. Should clinical experience, as well as experimental and epidemiologic research support such a conclusion, this would have a substantial impact upon public health.

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FROM THE FLOOR: I was wondering, do you all have a ...limit that when reached you will stop looking for biological effects? None have been found to this point. Are you going to keep looking until you find some or what?

DR. STRATMEYER: That it is a question that might be answered one way today and then a year later answered completely different. I might say that we have a very, very miniscule budget when you consider how much money, how many billions, were plowed into ionizing radiation bioeffects and how long it was in the ionizing business before really solid evidence came along. I can still remember the fluoroscopes in the shoe stores so it takes a while to get information and it also takes awhile after you obtain the information for people to look at it, investigate it and really believe it. There are a lot of effects there right now, but most people do not believe them at the present time and perhaps they will be refuted. We do not know but that is the type of thing that takes time in order to work out the problems in this area.

ULTRASOUND DIAGNOSTIC EQUIPMENT AND ITS USE

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

As an answer in part to the diagnostic use of ultrasound, we have to remember that we are talking about a pulse modality. If we do a few calculations we find that in fact sound is going into the body approximately 1 percent of the time. If we state that if we take 50 different slices of a patient, each slice taking 5 seconds to complete (and that is probably being very conservative because it probably takes less), we are talking about 250 seconds of total exposure time to the patient's total abdomen. If we multiply that again by 1 percent, you find that any sound (2.5 seconds over the total the body areas that have been scanned to find that any particular part of the fetus, mother, person being scanned) has a very short exposure time in any particular area. But we do stress you examine the patient quickly, you don't sit around with the transducer on the patient's abdomen and go off and have coffee or something, you have to be careful about it.

Ultrasound equipment, is in my mind, divided into three different categories; those which give us the so-called static images, those which are real time images, and third which is so-called duplex, and this is in all fairness a commercial term used by one or two companies relating a complex piece of equipment which we will discuss.

There are some 40-odd procedures ranging in area from the top of your head to the tip of your toes and so that if we say there are 40 procedures and each of those can diagnose say on the average 4 different types of pathology, you can see there is really a reasonable amount of pathology that can be diagnosed using diagnostic ultrasound.

The transducer of course, is the key element. But there is a real variety now. It seems that when you have to buy a unit, you have to buy five or six different transducers all of which are slightly different either in size and in frequency. The pictures 5 years ago, were totally different from what we have today. We have much better pictures, we also have a lot more information being obtained because of the electronic changes. In fact now when we do an abdominal examination, where 5 years ago the most we could hope for was a 2-1/2 megahertz transducer to get some reasonable images, we are now talking about using 5-megahertz transducers, which obviously increase our axial resolution. The interesting thing is that some of the companies are now working on electronics that will be able to use 7 megahertz and one company is even talking about the possibility of 10 megahertz for routine diagnostic work, which just means that our resolution is getting better and better all the time.

The key thing we want to stress is that these flat-faced transducers can be focused to minimize the vergence in depth. It can also be focused so that we have narrower beams to try and get better lateral resolution. So the transducer is the key element. The transducer puts out the burst of sound which will pass through tissues and upon reaching a differential acoustic impedance, some sound will be reflected back. That of course will be picked up by the transducer in a quiescent phase. The sound itself will be reflected back and converted from sound into electrical energy and that will be displayed on the oscilloscope.

In the way of explaining the complexity, if I were to make a simple block diagram with three blocks, you would think it is terribly easy and I like to make people believe it is not that easy. Figure 1 represents various components; RF amplifier, demodulator, and a whole bunch of different things. The key thing I want to attract your attention to is the lower left hand side of the figure where we seem to have a dentist's drill hanging there. That particular articulated orb has three joints so to speak. If you want to relate it to our own bodies, we are talking about shoulder, elbow and wrist. And in those are sine-cosine potentialities or equivalents which allow us to relate the position of the transducer in space back into the electronic system so that subsequently we will end up compiling the ultrasound information and the spatial information and that will give us a two-dimensional picture.

It is that two-dimensional picture that is important to use because that is what we have to look at to understand what is going on inside the body, otherwise the key thing ultrasonically we will do is try to look for anatomy and variations of such anatomy. So with all these boxes and electronics going along, we end up with a single picture which we will look at.

The static images; there are several categories; we could talk about so called "A" mode, that is the old radar term of course, for an amplitude modulated signal. That is almost a defunct creature nowadays, except for work being done by people who use "A" mode techniques and the amplitude modulated signals for looking in the eye.

"B" mode, however, brightness or intensity modulated signals, are used in two different places. One is the so-called TM mode, time-motion mode, which the cardiologists use predominantly for looking at the heart. We are not going to discuss that too much today. This particular technique converts the "B" mode intensity modulated signal, combining it with time and has the motion from the heart put on a stripchart recorder which the cardiologists then can interpret. The "B" mode scanner, however, is the one that we are particularly interested in.

Some of the equipment (Fig. 2) have so many lights on it that you think it really is a rocket going someplace. But this particular unit happens to be a real-time scanner. It has stripchart recording capabilities along the time motion to do at the bottom of the figure.

The static B mode scanner is commercially available (from different companies). Fourteen years ago when the Government built a B mode scanner, it cost $13,000, except that at that particular time the company we were dealing with then sold out to Picker and it was amazing how in a period of 2 days the price could rise $4,000, but it went from $13,000 to $17,000 over a 2-day period.

Some units run in a range of $68,000 to $70,000. All of the controls are just confusing, we are very sophisticated, however, now we even have a little alpha-numeric generators to put information on the screen. Basic electronics. One unit happens to have attached to it a scanning bib, a unit on an arm which will rotate around the bib supposedly facilitating examination of the patient. It is very fine when you are dealing with ambulatory patients, however, sick patients on stretchers are virtually impossible to do with this unit because you have to move the patient along.

The so-called Unirad EDP is a digital storage type unit but once again you can see all the controls. It contains a viewing TV screen above, a secondary TV screen for taking Polaroid pictures, although polaroid pictures are a thing of the past, and a small screen which depicts the A mode configuration. Sliding type controls are used to adjust the ultrasound data.

These buttons relate to the function of the cameras and the storage and doing fancy other things. The arm unit seems to be very large and cumbersome but actually it is one of the better ones out now.

The Analog unit; until recently, we had to deal with so-called bistable systems in which standard storage oscilloscopes were utilized. It was all very nice in those days. It wasn't all that unknown phenomena and a lot of data was lost. Subsequently analog storage systems were developed, which allowed us then a greater range of information to be displayed and this analog storage was all very nice, it got us into the so-called grey scale phase of ultrasound or image ranges, anywhere from black to white and in between. We got a lot more information back; less information was lost I should say, because of the storage device. The analog storage, however, had its problems and the problems were ones of drifting and maintenance. Analog video converters were notoriously susceptible to breakdown.

Figure 3 is an analog picture of a clinical case with the grey scale information. These particular scans were taken on an individual who was susceptible to adema and as a result developed an inflammatory process in the pancreas and subsequently ruptured those enzymes into the abdominal cavity and formed what is known as a pseudocyst. This happens to be a transverse section, slicing up like you slide bread and viewed from below, right hand side of the patient here anteriorally the back part of the patient. The key things that we see here anatomically in this particular area and the spine, the patient's abdominal aorta and the inferior vena cava; the diffusely speckled area. Each of those speckles represents sound coming back, so there is quite a bit of detail there. The really large area with no echoes at all which we were able to look at various sections, this is a sequence of changes in the appearance of this and this happened to be a psuedocyst in this patient. But this is the analog picture.

Figure 4 is a digital picture. You will notice that it seems to be a bit more grainy than in the previous analog picture. Part of that relates to the fact that the previous picture was stored on a matrix of about 1,000 by 1,000. Here we are storing on a matrix of about 512 by 512 pixels although we can get 32 shades of grey on this. So there is a little bit of a loss of the quality of the picture, although diagnostically it has not been changed. The commercial companies are now working on methods of smoothing techniques to smooth up the edges of the pixels. This happens to be multiple sections of a patient who was pregnant and happened to have a twin pregnancy. We started getting information about the twin pregnancy; we start counting limbs; one, two, three, four, five, six, maybe seven limbs all mixed up, and you know right away we are not dealing with a centipede but at least a multiple pregnancy. Further over here is another scan which shows you two major what we call blobs, humans are two-blobbed individuals (the head and the body), so we know we are dealing with a multiple pregnancy.

The difference between this of course and the other thing is that with the digital information, there is a microprocesser in there, and we have all sorts of other little things going on for us. For example, the transducer that was used, it is a long focused, 19 mm, that is an automatic function of equipment. We have the scale being determined, what scale size, we are talking about various angulation features which are all done automatically and it is a nice convenience but it is extremely stable and does not drift and needs very little attention.

Real time scanners are the scanners that are coming on very strong and probably in the next 2 or 3 years, will replace the big static scanners, because the pictures are getting better and better, and if you can do it on real time it is going to work out better. Real time means on-line visualization of information as you are obtaining it and seeing it right now. It is much like fluoroscopy, you can see it happening and there are various kinds of these real-time scanners, the first one that really came out with was a single transducer that merely wobbled in a sectoring fashion. That was a way which, in essence, if you scan the sector fast enough, you would develop imaging that would be real time. The next type that came out and the most interesting one that actually came out from Europe bomb scanner was a linear sequential, sequence of transducers in a long bar which would be sequenced very, very rapidly and we get two-dimensional--at least real time scanning. The more sophisticated phased array, a smaller transducer, electronically phased, find it differently to talk about it and then finally the so-called spinner where you have a transducer rotating very rapidly.

The Picker scanner; their so-called sector view, the scanning head, looks like an oversized hot dog except it is white. It has a transducer that will vibrate very rapidly and present to you a sector view of wherever you are looking. This works quite well I think, in part. We find some disadvantages--the vibratory pattern is such that when you finish the day, it is like you have been working on a jack-hammer. This gives information of 64 to 120 lines, depending how electronically adapted the equipment is, but for the first time in the United States, anyway we had something we could see. For example, the fetus moving around in the uterus, or we could see the kidneys move, or we could see the aorta pulsate as it was happening; it was very exciting.

The Unirad has a big bore with the transducers inside the plastic. This is all very nice, we find that it is in some part useful but we found that because of the size we are restricted to looking at relatively flat portions of the abdomen and when you get a pregnant lady with a very round tummy, it is very hard to make contact, so we lose information.

Two companies came out, initially, in the United States with a so-called phased array transducer assembly. In this instance, five transducers electronically were triggered through a microcomputer to fire either in sequence or for in-phase or out-of-phase. By firing them slightly out-of-phase, they were able to get the beam to sweep from one side to the next. So they developed a sectoring pattern electronically, rather than have anything physically moving.

These units do not do anything more than the standard sectoring units and they do cost quite a bit more. I do not know if you are really getting your money's worth with a $100,000 unit when you can get a unit that may cost you only $35,000.

The spinner transducers are relatively large units which are placed in contact with the patient's abdomen. In the unit are three transducers which will fire as they pass an aperture and we will end up with a sector, and we say, it will be real time.

Figure 5 is the real time unit with all the controls. This unit itself is interesting because you will find that this unit will plug in and become a duplexer which we will talk about momentarily.

Figure 6 is an image from it. You say "Gee; that does not look as good as what we had before," and you are right; it doesn't. It is not quite as distinct as what we have seen before on static imagers. Part of the problem is that to photograph this we have to put it into so-called digital freeze frame and we lose some of the apparent resolution. Although what we are looking at here now is the section of a patient's liver. This is the diaphragm, this diffuse area is the liver itself, this dark area here happens to be an hepatic vein. This is a gross enlargement of a hepatic vein. This particular one, parts of it measured up to almost an inch in size and this lady was in right-sided heart failure. But yet we can go ahead and see billary ducts that are as small as 3 millimeters, 2 millimeters in size with this particular unit. Sometimes it is hard to photograph them, but when you see it as you sweep back and forth it is very effective in identifying structures.

The duplexer is a combination of real time scanning and pulse doppler, which is tremendous for cardiovascular disease.

One unit functions by having scanning transducers spinning around through an aperture to visualize a vessel. Secondarily, there is a doppler transducer set up at the side in which you can see a peripheral beam running through the field. You specifically select a sample volume within the vessel and analyze that. At the same time, they can also look at the heart and look inside the heart to do pulse doppler. While they are doing the pulse doppler they can then do the time motion recording and get recordings of structures inside the heart. This happens to be a mytriol valve so that particular unit has got an awful lot of various functions and probably is worth its $85,000 cost.

A new unit that is now coming out on the market as a result of a demand for something that can scan the breast. As you are aware of the fervor of mammography and breast scanning and, not the edict, but the suggestion that patients from 35 to 50 years of age don't be routinely screened. It is unfortunate because of course there is a high incidence of cancer in those patients which would never is picked up once its there. It has created a lot of fervor and really activity in ultrasound companies to develop scanners that can look at the breast. With one particular unit, the patient lies with the breast dependent in the water.

It functions by having two transducers which basically are sectors. They each will do a sector from a different view in the breast and then rotate in increments around the breast as the breast hangs dependent and will have overlapping sector views. This information as it is being taken in 1 millimeter sections or one-half millimeter increments, is stored onto a video disk, the video disk is then played back rapidly and we have the effect of running through the breast and getting information that way.

As the videotape is played back, the orientation of the breast is opposite to how the patient actually was lying. She was lying with the breast dependent but it is easier at times to view the breast the opposite way, orientation being that we are used to looking at patients lying on their back. You can see the outline of the breast, the echoes inside are going to create a problem because all of a sudden we have echoes inside the breast that nobody really knows what they, in part, relate to. The motion we see actually is a local event occurring in the video disk going back and forth over an area of the video disk so that if we want to concentrate on an area of specific viewing one can.

This particular patient (Fig. 7) has a history of cystic and proliferative disease and if one looks close one can see small holes inside. Scans are being taken at 1-millimeter intervals, one a second, put on the video disk and then played back in this fashion, so that very quickly you can survey the whole breast. This is something that is not otherwise available. But the technique that is being used today is compiling 200 and 300 pictures, then having to manually go through those pictures and try to find things. I think that this is going to be the solution to screening breasts, especially in the age group where we don't do routine screening.

This is a review of something relatively new. Our only concern is that we hope the company doesn't go broke before it gets it out on the market. The development of this unit took longer than they had anticipated and I think they are a little bit tight. I think this unit is going to certainly serve its purpose, plus it is being modified to do both abdominal scanning and obstetrical scanning.

DISCUSSION

MR. NEUWEG: I was wondering if you think the use of the new real-time scanner will replace fluoroscopes.

DR. BROWN: No. I think that is probably the simplest way because I think we have to stop and say what do you look at in fluoro. I think that with most procedures, the G.I. procedures, with barium put in them, we cannot do anything like that at all. While we can look at more solid structures and while we can see soft-tissue formation, there is a whole area that we cannot touch right now, and that is the intestinal tract in terms of identification of ultraluminal process or anything that goes along with that. I really think that it is not really going to change that but will augment our capabilities. We find that with this real-time scanner we can go ahead and give the clinicians a bit more information, a bit easier. For example, if you have a patient who is up in ICU and they are concerned for example, maybe the diaphragm is not working right, maybe there is subphrenic abcess, there is no way you can fluoro over there, but you can take the unit to the patient and you can actually see the diaphragm moving.

Concerning amniocentesis and ultrasound, while some people do use a transducer with a hole in it and put the needle through the hole I think you will find that the majority of people use ultrasound to localize a point on the abdomen and then amniocentesis will be carried out without the ultrasound. This is the way we do it and it saves a lot of time unless you are doing it yourself. If you have one obstetrician coming in to do the procedure then it is just an extra pair of hands around and it gets very awkward. It is easier just to give them a spot and they now have faith that they will put the needle where they are supposed to put the needle.

FROM THE FLOOR: Any comments on the minimum resolving capabilities of ultrasound and any applications in mammography?

DR. BROWN: .....has done probably a good portion of work, although at times I do not know how far it has gotten. But he has shown that he has not been able to pick up the very small things like a microcalcification. There is no way that ultrasound will do that. I think the thing that he has been able to show is that there is such a reaction around a small malignancy and what you start to pick up is the tissue reaction. The malignancy itself is not picked up but you pick up the tissue reaction of approximately one-half centimeter size and possibly before it is palpable. I can only say that on this scanner so far, I have seen one-half centimeter cysts, perhaps a bit smaller, clearly. A lot of work has to still be done on that to develop a good base. There is so much information concerning all of that. You have to determine what is fibrous tissue, what is fat, and that is still a problem with the technique.

ULTRASOUND POTENTIAL AND NEW APPLICATIONS IN MEDICINE

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The current uses of diagnostic ultrasound are widespread and there has been tremendous increase in its availability and usefulness over the past few years. This has been primarily because of improvements in technology with the addition of Gray Scale and digital scan converters as well as improvements in transducers. The other aspect is the tremendous increase in knowledge about the diagnostic abilities of ultrasound and a proliferation of knowledge regarding interpretation of sonograms. It is also a way of imaging organs and structures within the body without exposing the patient to ionizing radiation, and although I cannot say that it is completely safe, I would certainly consider it relatively safe compared to almost anything to which we are exposed in our lives, including our cars, houses, walking on city streets, or smoking. However, we are being careful with it and have under our own aegis stopped the use of demonstrations using live models, reduced the exposure of fetuses, and generally are doing everything that we can to use as little ultrasound as possible consistent with obtaining medical diagnoses.

I would like to review the current uses of ultrasound for you and give some examples of how this modality has proven to be so valuable in today's medical practice.

The types of diagnostic ultrasound in use today include the A-mode (or amplitude modulation), B-mode (or brightness modulation), scanning (which combines the B-mode with motion or drawing of a continuous picture) and real-time ultrasound, which is in many ways comparable to fluoroscopic examination with x rays.

ECHOENCEPHALOGRAPHY

Starting out at the head, we have one of the oldest uses of ultrasound; that is, determining the position of the midline of the brain. This type of examination has been around for at least 20 years and still has value in making a quick determination of the presence of a space-taking lesion within the head causing a shift of the midline of the brain. Correlation with arteriography, particularly in the venous phase, has been quite satisfactory, and this method is still valuable for use in small hospitals or in situations where there is no immediate availability of a neurosurgeon or computed tomography for definitive diagnosis.

One of the other uses of this method has been in evaluating ventricular size, particularly in children. Because of the thinness of the skull, we can frequently obtain a consistent echo from the lateral wall of dilated ventricles, giving satisfactory correlation that can be used in diagnosing hydrocephalus or in following these children following shunt procedures without exposing them to radiation.

OPHTHALMOLOGIC USES

Specialized instruments for scanning the eye give a beautiful outline of the ocular structures and have been invaluable to the ophthalmologist in determining the presence or absence of lesions when there is cataract preventing direct examination or when the chambers of the eye may be filled with opaque fluid such as blood. In retinal detachment, sonography provides an immediate diagnosis for the ophthalmologist who can be assured that there is no tumor lurking behind the detached retina. This cannot be determined by other methods.

ABDOMEN

In the abdomen, there has been profound change in the approach to both normal and abnormal anatomic relationships on the part of radiologists and surgeons because of the ability to visualize structures in different planes better than has been previously possible. Excellent visualization of the upper abdomen is obtained with a normal liver having a homogeneous pattern of echoes. The renal outlines are well seen with considerable echo information available from the fat in the peripelvic region. Excellent visualization of the bile duct, head of the pancreas, and vascular structures is obtained without injection of contrast material of any kind. Within the liver itself, various disease states and conditions are identified which would not be possible by the usual radiographic methods without invasive studies. Metastatic disease, primary tumors, such as hepatoma, and abscesses can all be identified and in many cases correctly diagnosed because of distinguishing characteristics of various solid and cystic masses. The status of the biliary ducts secondary to extrahepatic obstruction can also be determined. There is also good visualization of the systemic hepatic veins in congestive failure, an area which is somewhat obscure by almost any other method of study except for very selective arteriographic procedures.

The gallbladder is one of the organs most amenable to examination by ultrasound. This examination is performed by obtaining both longitudinal and cross-sectional scans through the upper abdomen as well as oblique and erect views when needed. The classical appearance of gallstones is that of very dense echoes from within the lumen of the gallbladder with acoustic shadowing extending out in a band behind the gallbladder. This is not dependent upon calcification of the stones. In cases where there is some question, erect examination of the gallbladder will show shifting of the movable gallstone within the gallbladder. Stones impacted in the cystic duct area can be identified, and there is also evidence of thickening of the wall of the gallbladder, a feature which is not usually available by any other diagnostic modality. This has been correlated with chronic cholecystitis in the absence of stones. For years the presence of sludge with calcium carbonate crystals found in biliary drainage has been considered to be evidence of chronic cholecystitis, but with ultrasound examinations over the past few years, it has become very evident that many gallbladders in otherwise normal patients contain what we call sludge or thick bile. This has been shown not to be evidence of disease in most cases. Distinguishing the presence of calculi within the common duct is very difficult on ultrasound since air in the duodenum, which lies adjacent to it, can frequently obscure this area. Occasionally, however, these can be identified. The measurement of the duct can also be very accurate and give indication of distal obstruction.

Using ultrasound for examination of the gallbladder has been at least as successful as cholecystography using contrast material, and from recent studies in the literature, it is probably more accurate. Ultrasound has been particularly helpful if the patient has a nonfunctioning gallbladder after a single dose of contrast tablets. The patient can be examined immediately, thus saving the patient an extra dose of contrast tablets, the problem of coming back the next day, or an extra day's hospitalization for a diagnostic procedure. It is also a great advantage when oral cholecystography cannot be done because of jaundice, liver disease, vomiting, or diarrhea.

Another abdominal condition which is much better diagnosed by ultrasound than x ray is the presence of ascites. Since ultrasound is an extremely good indicator of the presence of fluid, ascites will show up as echo-free zones lateral to the abdominal organs and in many cases will outline the gallbladder and other structures, allowing us to see both sides of the walls of these structures.

Evaluation of the pancreas has also proven to be extremely valuable although over the years radiographic methods have been extremely difficult and generally unsuccessful. The normal pancreas has a somewhat diffuse echo pattern, usually less echogenic than the liver, and can be seen just at the end of the distal bile duct lying over the inferior vena cava with the body over the aorta. On transverse sections the pancreas can be visualized in its entirety as a sort of S-shaped or U-shaped structure lying in relationship to the aorta, vena cava, and superior mesenteric artery. Occasionally, a normal pancreatic duct can be visualized.

In pancreatitis, the organ is usually swollen and slightly less well marginated with a more sonolucent appearance over the entire organ. The calcification seen in chronic pancreatitis lines up within the duct, but ultrasound is not superior to x ray in determining the presence of calcification. One of the great advantages of ultrasound is the ability to repeat this examination as frequently as needed, showing changes in the size of the pancreas with clinical improvement. One of the complications that develops in pancreatitis is the presence of pseudocysts. These may be fluid filled or contain some debris. In the past, these have been uniformly operated upon immediately, but with our ability to repeatedly examine patients for this condition, it has been shown that they vary considerably in size and may disappear spontaneously much more often than was previously thought. This, in many cases, has saved the patients very complicated and extensive surgery. Carcinoma of the head of the pancreas can also be diagnosed by ultrasound with a good bit of secondary help from visualization of bile duct dilation secondary to extrahepatic obstruction. This is an early way of making the diagnosis rather than putting the patient through a very extensive work-up. Using ultrasound as the original diagnostic tool, you can frequently make the diagnosis within one or two days, whereas in reviewing past hospital records, most carcinomas of the pancreas were not diagnosed until the tenth or eleventh day of hospitalization. This may not cause a decrease in mortality from carcinoma of the pancreas, but in combination with needle aspiration of cells or biopsy guided by ultrasound, this can make a difference in length of hospitalization, the ability to eliminate many unnecessary diagnostic studies, and possibly saving the patient laparotomy. This all represents considerable saving in trauma and money for both the patient and hospital.

RETROPERITONEAL

In the retroperitoneal area, there is excellent visualization of the aorta, and this gives us the ability to diagnose the presence of small aneurysms without invasive procedures and to re-examine known aneurysms for possible leakage. This can be used following surgery with prosthetic grafts to determine their patency. Ultrasound has been of considerable value in delineating renal disease. The normal renal outline can be well seen and measurements made, particularly important in patients with diminished renal function or in association with localization purposes for needle biopsy of the kidney. Again, differentiation of masses within the kidney has been highly accurate and, associated with ultrasonically guided aspiration and cytologic study, has reduced the need for surgery in innumerable cases by proving the presence of benign cysts. These cysts are sonolucent with no internal echoes and excellent through transmission of sound. Multiple cysts can be identified. In carcinoma of the kidney, a solid mass will be seen with multiple echoes within the kidney. Ultrasound will also allow us to make rather definitive diagnoses in extensive disease and spread of renal carcinoma with liver metastases and extension of tumor into the vena cava, growing up toward the heart. It also allows us to examine a well hidden area around the kidney which has been very recalcitrant in terms of visualization. Perirenal hematomas following medical procedures or trauma as well as perirenal abscess can be easily diagnosed by ultrasound. Within the kidney, the presence of hydronephrosis can be very well determined and a good estimate of the degree of hydronephrosis made by showing separation of the peripelvic and calyceal echoes. This is extremely important in conditions where the patient may be allergic to contrast material or where there is diminished kidney function and intravenous pyelography would be of no value. Metastatic disease from the kidney and elsewhere in the retroperitoneal area can get behind the aorta and displace it. This is an extremely difficult area to evaluate by the usual radiographic methods although computed tomography could obviously show this at considerably greater cost.

PELVIS

Within the pelvis, in evaluation of the bladder, gynecologic problems, and particularly obstetrical conditions, ultrasound has represented a major advance because of the absence of ionizing radiation. Within the bladder, one can visualize considerable detail. A rather rare case of hemangioma of the bladder presented on an intravenous pyelogram suggests a tumor, but on the cross-section of the bladder by ultrasound it can be seen that this large echo-free mass is separate from the wall of the bladder in most areas. Outline of the pelvic organs has been extremely satisfactory and again replaces an invasive procedure with the use of either contrast material or air outlining various pelvic structures. The presence of intrauterine devices can be accurately determined as well as their exact localization, something not available on routine x rays. The presence of ovarian cysts presenting as sonolucent masses and abscess cavities extending down into the cul-de-sac are other examples of lesions well seen by ultrasound. Unusual tumors of the pelvis, such as teratoma, can often be very accurately determined lying behind the uterus because of their very dense echoes or because of the presence of fluid levels from the presence of fat within the mass.

In obstetrics, the absence of any ionizing radiation makes this an extremely safe method of evaluating all stages of pregnancy. Gestational sacs can be identified within 5 to 6 weeks of the onset of pregnancy, and ultrasound is sometimes responsible for picking up unsuspected lesions in association with pregnancy. A normal pregnancy can be monitored repeatedly if necessary, showing the exact location of the placenta and the size of the fetal head, which can be measured and correlated with growth rate. In some cases even diagnoses of the sex of the fetus can be determined. Multiple pregnancy is easily diagnosed. The various abnormalities of the placenta are very amenable to this method of diagnosis, and there really is no other satisfactory way of evaluating problems such as placenta praevia or abruptio placentae when this condition is not catastrophic and allows time for any type of examination. A line of separation can be seen between the uterine wall and the placenta. The presence of molar pregnancy is also easily diagnosed, although in some cases there may be some confusion with large degenerating placentas. Tumors within or associated with the fetus, such as sacrococcygeal teratomas, can be identified in utero, and occasionally a rare condition, such as the Eagle-Barrett syndrome (with absence of abdominal musculature, hydronephrosis, and hydroureter), can be diagnosed prior to birth.

In the chest area, ultrasound has been used to guide thoracentesis and for evaluation of mediastinal masses. Newer methods and equipment can give very good visualization of the breast outline and underlying abnormality within the breast, such as carcinoma and cyst. The development of computed tomography for ultrasound can also show the presence of these lesions, but ultrasound has so far been unsuccessful in determining the presence of microcalcifications, which would be vital if ultrasound is to be used for mass screening. Hopefully, the use of varying frequencies and through transmission techniques may eventually lead to some solutions of this problem.

The evaluation of cardiac disease represents an entire new field of approach to those conditions and allows the visualization of the heart in cross-section or longitudinal section or in any plane desired with actual visualization of the valvular structures, myocardial wall, and other aspects of heart disease.

In summary, the use of diagnostic ultrasound has provided an entire new field of medical imaging and has been extremely valuable in examining portions of the body that require differentiation between different types of soft tissue. It allows us to examine the body and fetus without exposure to ionizing radiation and in many cases without requiring any invasive type procedure. One of the great needs in ultrasound is obviously the standardization of procedures and equipment, but along with this, the tremendous improvements in technology and computerization place ultrasound in a very exciting position for safely evaluating structures within the body.

DIAGNOSTIC ULTRASOUND OUTPUT LEVELS and QUALITY ASSURANCE MEASUREMENT TECHNIQUES

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(Presentation made by Dr. Stephen W. Smith, Division of Electronic Products, Bureau of Radiological Health, FDA.)

INTRODUCTION

Diagnostic ultrasound is now widely accepted as an indispensable diagnostic tool with demonstrated benefits in neurology, cardiology, obstetrics and gynecology, ophthalmology, and other fields of clinical medicine.

Because of the wide use of diagnostic ultrasound procedures and unanswered questions with regard to the potential risk that may be associated with this modality, it is advisable to maintain the acoustic output of such devices as low as feasible while obtaining the maximum adequate information. In this regard, knowledge of the output and the use of quality assurance techniques to evaluate imaging capabilities of machines is important. In this discussion we will look at available measurement techniques that can be used to measure the output of diagnostic ultrasonic equipment, review some reported levels from diagnostic machines, and discuss these in relation to reported biological effects information. In addition we will review the use of quality assurance test procedures to assist in assuring optimum imaging capability of machines in clinical use.

MEASUREMENT TECHNIQUES AND INSTRUMENTATION

From a practical standpoint there are basically two types of measuring instruments available. First, those that measure spatial average quantities, that is, total power and second, those that measure point field quantities and thus provide a capability to determine the local values of the intensities within an ultrasonic field. We will discuss radiation force techniques for making total power measurements and commercially available hydrophones for determining intensities within a field from commercially available ultrasound equipment. The types of ultrasound diagnostic equipment available includes obstetrical doppler units to monitor the fetus, peripheral vascular units to measure blood flow, single element pulse echo units commonly used to image structbody and real time phased, linear and annular array systems.

Total Power Measurements

The radiation force technique is the most universally used measurement method today for determination of total power. It is a relatively simple, convenient and accurate method for determining the total power of an ultrasonic field. There are commercially available instruments capable of measuring output levels in both the diagnostic and therapeutic range.

The principle of radiation force is based on the fact that a traveling plane wave ultrasonic field subjects the propagating medium to increases and decreases in pressure. Since the properties of the medium are different during the compression and rare faction phases, a unidirectional force is produced, known as radiation pressure. One of the advantages of the radiation force technique is that the force produced is independent of frequency. In addition, it is an absolute measurement method in that the acoustic power can be directly related to the gram weight. For example, for propagation in water, a traveling plane wave beam of 1 mW of power exerts a force of 6.57×10^{-7} Newtons in the direction of propagation (equivalent to the weight of 0.067 mg) on a perfectly absorbing target. As illustrated in Figure 1, for a reflecting target, the force produced in the direction of propagation varies as the square of the cosine of the angle (θ) between the normal to the reflecting surface and the incident ultrasonic beam axis and is equal to an equivalent mass of $0.136 \cos^2 \theta$ (gms/W). The relation between the force produced and power for conditions as illustrated in Figure 1 is

$$F = 2\, P \cos^2 \theta / c$$

where c is the velocity of sound in the medium.

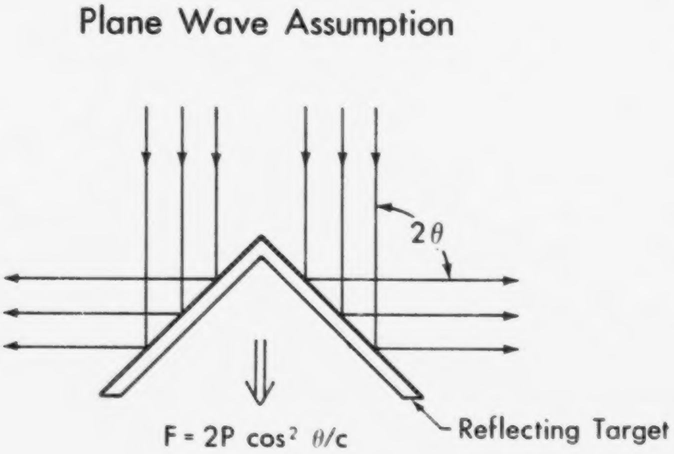


Figure 1

One of the more common techniques for measuring the total output power from diagnostic instruments has been the use of sensitive analytical balances using either absorbing or reflecting targets. Such a system, used in the BRH laboratory, is illustrated in Figure 2. Measurements are made by mounting the ultrasonic transducer whose output power is to be measured directly over the target. When the transducer is energized, the ultrasound beam from the transducer strikes the reflecting target and the radiation force in the direction of propagation is measured using the precision balance. It is important that the size of the target be larger than that of the ultrasonic beam to insure intercepting the entire ultrasonic field. As mentioned previously, such a system can be calibrated using weights, thus providing an absolute measurement method.

Several prototype portable radiation force type instruments for use with diagnostic equipment have been reported in the literature (1-5). At the present time, to the best of our knowledge, there is only one commercially avaiablle diagnostic range wattmeter (the U.M.A. ultrasound radiometer). It uses the radiation force principle to measure average power. The Bureau is currently testing and evaluating this instrument (32).

A description of the operation of the U.M.A. ultrasound radiometer has been reported in the literature (1). It is a force feedback device in which the force caused by the incident ultrasonic beam upon the target is balanced by the torque developed by a meter movement which supports the target. The motion of the target is measured by a photoelectronic sensor and is fed back as current into the meter movement. The mechanism is neutrally buoyant and is entirely submerged in isopropanol in an enclosed tank. The ultrasonic beam is directed into the tank onto a reflecting target through a thin 25 mm diameter Mylar™ window and, after reflection from the target, the ultrasound is absorbed in a rubber pad to prevent standing waves. The average power range of the UMA radiometer is 1 to 100 mW. Both CW and pulsed ultrasonic fields can be measured with this device, if the power is taken as a time average value. With pulsed equipment, because of inertia, such a radiation force instrument cannot respond to rapid temporal variations in radiation force, thus the time average value of the power output is measured. The measured parameter referred to for both CW and pulsed equipment is usually the temporal average ultrasonic power output. The relation between the peak and temporal average power is illustrated conceptually in Figure 3.

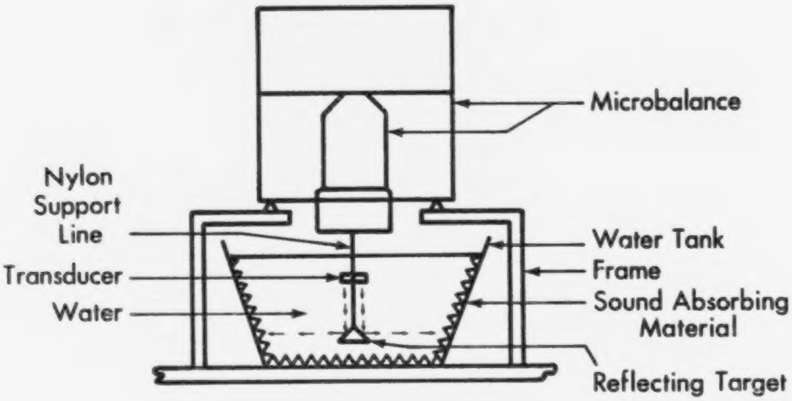


Figure 2

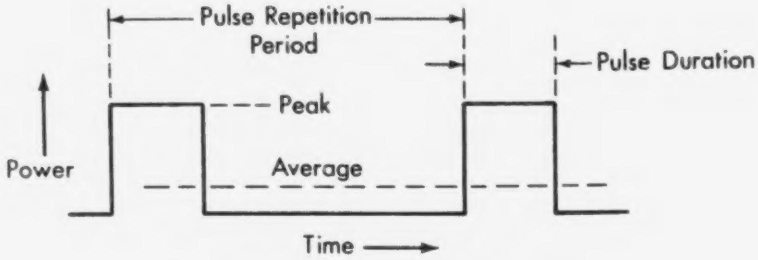


Figure 3

Intensity is a parameter of uppermost importance in the consideration of biological effects. Intensity (sometimes referred to as power density) is usually expressed in mW/cm^2. An intensity commonly measured is the spatial average temporal average (SATA) intensity. It is normally determined by measuring the total power in an ultrasonic field as measured with a radiation force system and dividing this by the area of the ultrasonic field.

In measuring the actual intensity distribution of an ultrasonic field, complicatons may arise because the intensity is not uniform throughout the ultrasonic beam and varies with time. Several quantities can be specified. For example, the maximum acoustic intensity with regard to space and time can be determined. This is generally expressed as the spatial peak temporal peak (SPTP) intensity.

Another quantity that can be determined is the spatial peak temporal average value (SPTA). This is the intensity at the positon in the ultrasound beam of the spatial peak, averaged over time, and is a quantity often referred to in discussing data on biological effects. If the SPTA intensity is in the mW/cm^2 range, the SPTP intensity is in the range of W/cm^2 since the duty factor for pulse echo diagnostic machines is usually in the range of 1/1000. The spatial peak temporal average intensity for non-focused transducers is maybe several times higher than that of the spatial average temporal average intensity. For focused transducers the spatial peak intensity may be many times higher than the spatial average intensity at the face of the transducer.

The relation between the various intensities discussed above is illustrated conceptually in Figure 4.

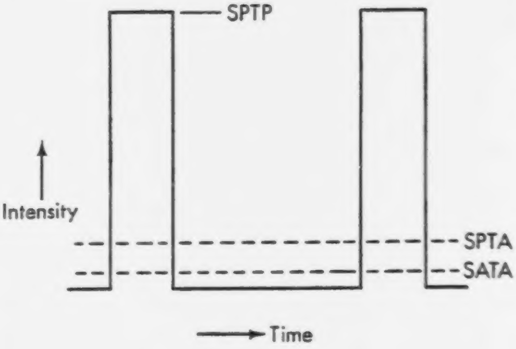


Figure 4

DEVICE OUTPUT LEVELS

While most manufacturers do not currently provide output information with their equipment, ultrasonic intensity levels and total power output measurements of commercial diagnostic instruments have been reported by several investigators (6-10). Table 1 and Figures 5-11 summarize output levels from various types of diagnostic devices. The data for these curves were taken from the literature, from reports submitted by manufacturers to the Bureau of Radiological Health (BRH) and from measurements by the BRH.

Table 1. Summary of output levels from various types of diagnostic ultrasound

Type of unit	Total power (mW)				SATA at transducer face (mW/cm^2)				SPTA (mW/cm^2)				SPTP (W/cm^2)			
	#	Min.	Max.	Mean	#	Min.	Max.	Mean	#	Min.	Max.	Mean	#	Min.	Max.	Mean
Pulse-echo scan	64	0.1	21	5	53	0.07	10	3.4	12	9.6	169	60	19	.05	1699	279
Pulse-echo real time	3	2.1	562.7	315	9	0.3	10	8.2	2	0.014	0.058	0.031	9	.4	130	22
Obstetrical doppler	14	1	37	9.6	16	0.24	20	6.3								
Peripheral vascular doppler	8	5.7	105	32	10	10	840	203								

*Means number of units in each category

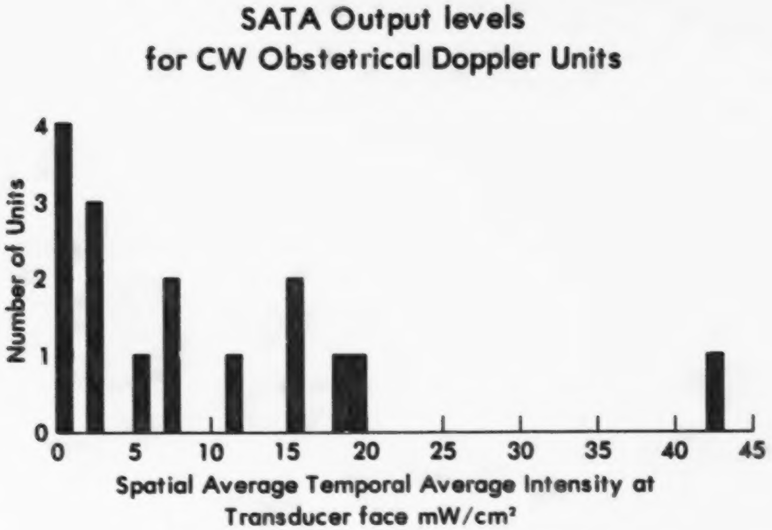


Figure 5

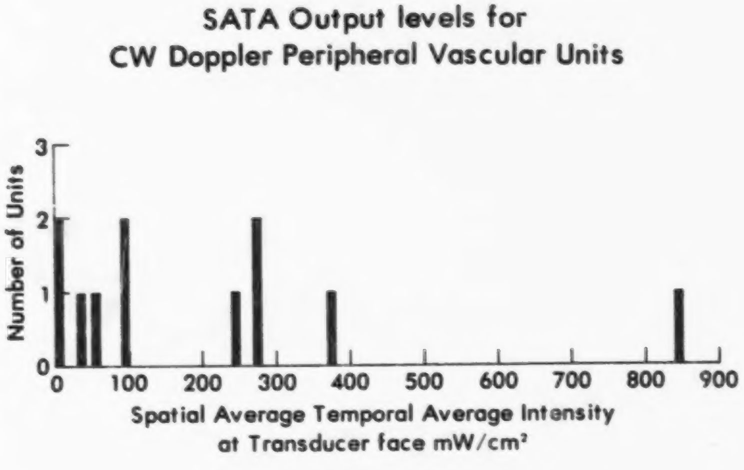


Figure 6

The spatial average temporal average (SATA) output levels at the face of the transducer for CW obstetrical doppler units were categorized in increments of 1 mW. More units for this set of data fall within the category of 1 mW or less than any other single category and 47 percent of the values are 3 mW or less. This data indicates that obstetrical doppler units can be designed to operate at relatively low output levels. This is particularly important since these are used for fetal exposures.

The lower output levels (on the order of a few milliwatts) support Ziedonis in his indication that obstetrical doppler equipment can be designed to operate at levels well below 5 mW per cm^2 (12). In addition, Endo et al. have reported a technique for modification of commercial doppler equipment to reduce the acoustical intensity required from 8 mW per cm^2 to 1 mW per cm^2 (13). This represents the type of approach that should be encouraged in the manufacturer of diagnostic ultrasound equipment; that is, designing equipment with satisfactory performance and with as low an acoustic intensity as feasible consistent with obtaining needed diagnostic information. Such an approach requires attention to the original design of the equipment since it is obvious that a simple reduction of ultrasonic output will probably result in unsatisfactory performance of the equipment unless the signal-to-noise ratio is also improved. In addition, output information should be routinely provided with equipment so the user can make informed judgments in selecting equipment and in evaluating the health benefit risk implications of the device in use.

Figure 6 presents the spatial average temporal average output (SATA) levels at the face of the transducer for CW doppler peripheral vascular units. The reported output levels in this set of data range from 10 to 840 mW per cm^2 with an average output of 203 mW per cm^2. The maximum output level was reported by Farmery (4). The output levels from cw peripheral vascular doppler units are comparatively high relative to obstetrical doppler units as shown in Figure 5. This is due in part to the greater sensitivity which is required to detect the small signals received from blood flow. However, more than half the units operated at levels less than a 100 mW per cm^2, indicating that many of the devices reported could probably be designed to operate below some levels in this set of data.

Figure 7 presents the spatial average temporal average (SATA) output levels at the face of the transducer for single element pulse echo A and B scan units. The minimum, maximum and mean SATA intensities for the 53 data points were 0.07, 10 and 3.4 mW cm^2 respectively. For this set of data, more were in the category of output intensities less than 1 mW than in any other single group as characterized in 1 mW increment output levels as is

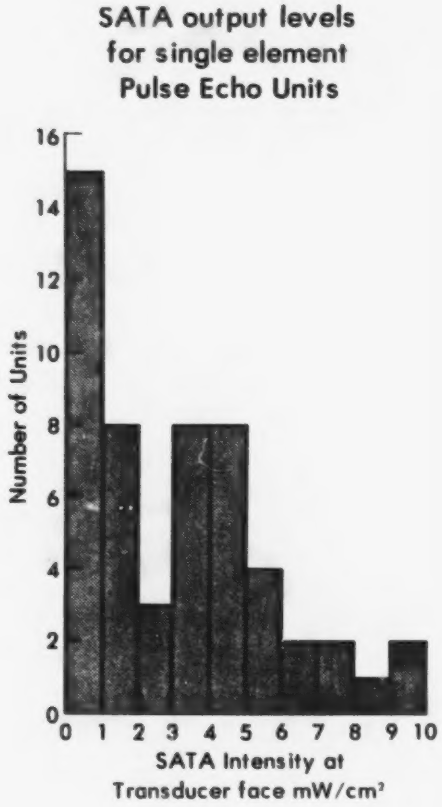


Figure 7

done in Figure 5. Forty-nine percent of the SATA output levels were 3 mW/cm^2 or less. These are intensities at the transducer face but the exposure levels would be greater for those units using focusing transducers if the intensity were measured at the focal distance as discussed in the section under intensity measurements. For example, assuming a typical transducer, 13 mm in diameter is focused to a beam diameter of 7 mm thus making the area 3.5 times smaller, the spatial average temporal average (SATA) level at the focal distance, neglecting absorption, would then be approximately 3.5 times greater than that at the face, and of course the SPTA and SPTP intensities of both would be even greater. For purposes of comparing the output levels with biological effects data the intensities at the focal distance should probably be considered. Thus manufacturers should supply the beam area both at the face of the transducer and at the focal distance. The beam width at the focal area is also important from the standpoint of the resolution capability of the device. Figure 8 presents the spatial peak temporal average (SPTA) output levels for single element pulse echo units. Although there exists little data in this category there is a wide spread in the distribution of intensities. This is partially because some transducers are focused and others are non-focused.

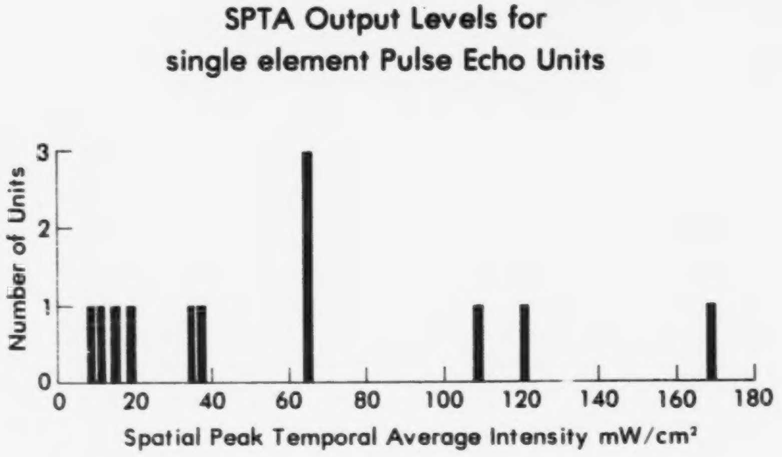


Figure 8

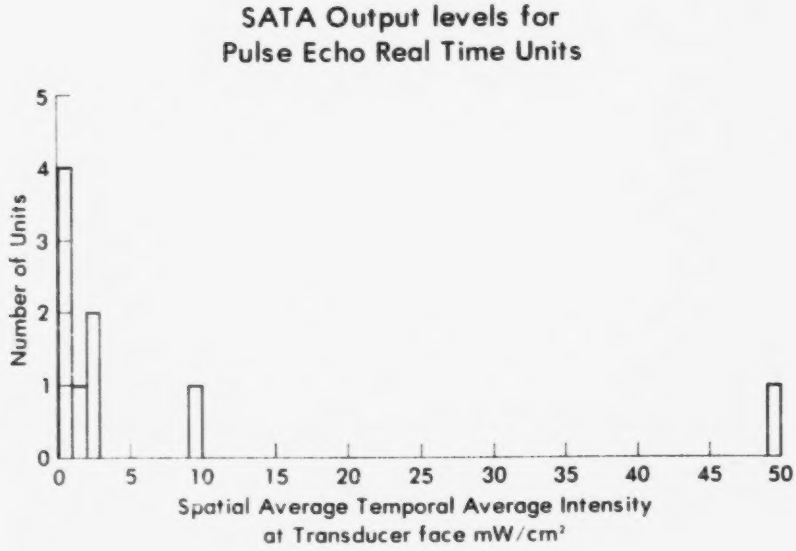


Figure 9

BEST DOCUMENT AVAILABLE

Table 1 has the spatial average temporal average (SATA) output levels for real time pulse echo units. There are relatively little data in this category. All units except two are linear arrays. The unit with an output level of 50 mW per cm^2 is an annular array system and is different in design than the other units in this category. Figures 10 and 11 present the spatial peak temporal peak (SPTP) output levels for single element pulse echo units and real time pulse echo units respectively. The spatial peak temporal peak (SPTP) intensity levels for pulse echo machines are in the watt cm range while the temporal average values are in the mW/cm range.

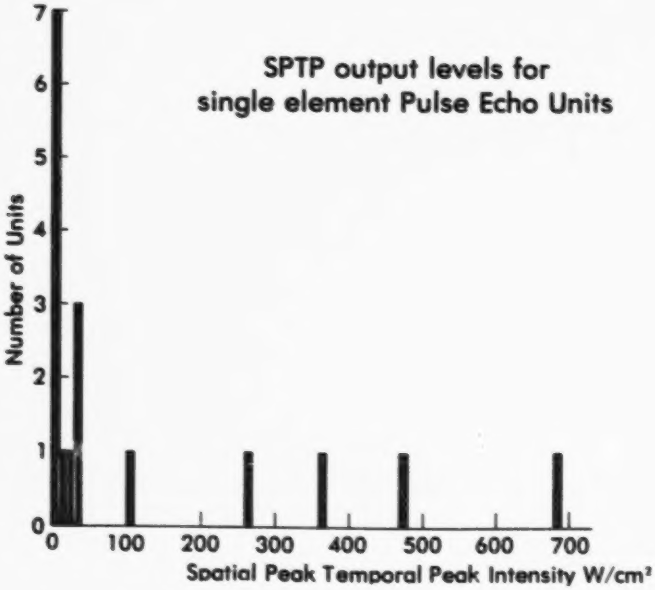


Figure 10

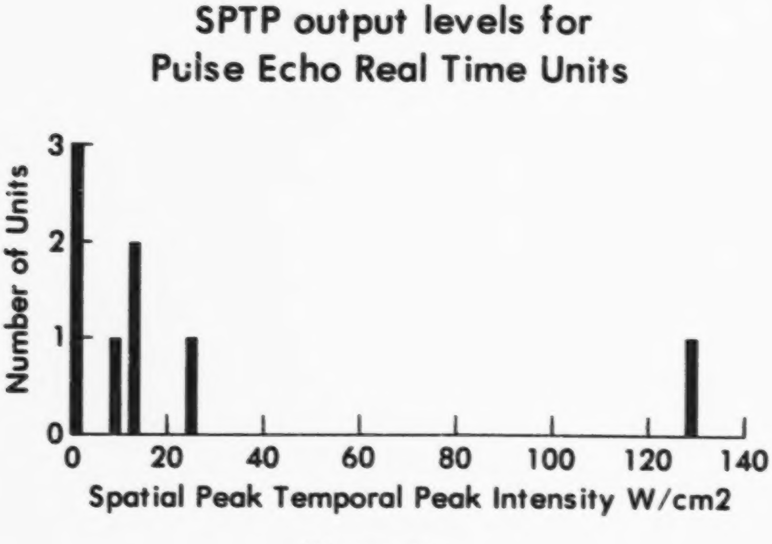


Figure 11

It is informative to compare output levels from diagnostic ultrasound equipment with reported biological effects. This can be done by utilizing the results of summary analysis curves developed by various investigators along with some recently reported bioeffects data.

A number of review articles on the biological effects of ultrasound have been prepared such as those of Ulrich, Wells, Nyborg, and Stratmeyer (14-17). Many of these reviews present results from many workers in the form of temporal average intensity versus time. These curves provide a graphical summary, in a selective manner, of the data available at the time they were constructed. A comparison of these various curves has been reported in the literature (18).

Presented in Figure 12 is one such curve adapted from the reviews of Nyborg (16). This curve in the format presented here is a plot of spatial average, temporal average (SATA) intensities as a function of total elapsed exposure time. Although this curve does not define a threshold value, perhaps it does provide some information with regard to those levels above which some potential risk may be involved. In addition to the summary curve in Figure 12, a few other reported biological effects not used in the development of this curve are also plotted. (21-24). The maximum and average output levels reported for the various types of diagnostic units are also indicated on this curve for purposes of comparison. A more complete discussion of the biological effect data is reported in the bibliography (17,19,20). Figure 12 illustrates that some diagnostic ultrasound devices are capable of operating above the levels at which some biological effects have been reported.

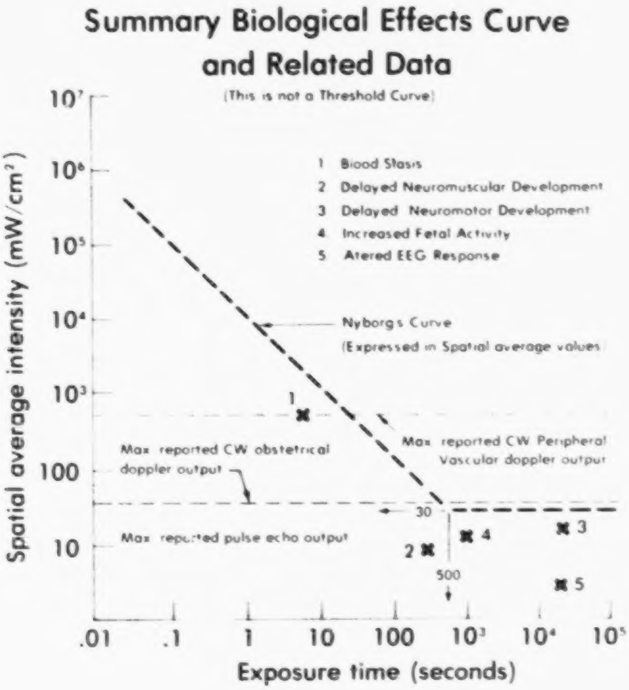


Figure 12

The highest output levels reported are from peripheral vascular units. It is interesting to note that the maximum output level of 840 mW per cm^2 is in the range where blood stasis has been demonstrated (23). Concerning CW fetal doppler exposures, one of the interesting biological effects reported is that of David et al. of increased fetal activity in pregnant women upon exposure to diagnostic ultrasound (24). Other investigators have not been able to confirm this effect (34,35).

Concerning the output for pulse-echo units, the SATA intensities at the face of the transducer transducer as seen in Table 1 can be expected to range from about 1 to 10 mW/cm^2 with the SATA intensities at the focal distance somewhat higher. The reported effects of long-term exposure on the chest muscle, myocardium, and liver in experimental animals at pulse echo intensities of 10 mW/cm^2 call into question the advisability of the routine repeated exposure of the liver by service men for purposes of checking the imaging capability of pulse-echo units (26).

In terms of SPTP intensities, these levels are high even with respect to therapy levels. This raises the question as to whether some biological effects may be related to temporal peak intensity rather than to temporal average intensity. In this regard it is interesting to observe that several of the recent biological effect data reported in vitro have used diagnostic ultrasound devices (17,25,37). Lewin has also recently reported bioeffects which could, to a certain extent, be related to the pulse repetition frequency (33). Whether the mechanism for such effects are related to peak or to average intensities has not been established at this time. However, recent data by Carstensen and Child on the effects of ultrasound on drosophia point to the possible importance of peak intensities in relation to some biological effects (36). The spatial peak temporal peak (SPTP) output levels of diagnostic ultrasonic equipment may require more careful consideration in the future. At present, it would be prudent to maintain as low a peak intensity as practical. Such considerations should be included in the design of such equipment. One approach along this line, i.e. to design diagnostic ultrasonic imaging equipment for exposure reduction, has recently been reported (27).

QUALITY ASSURANCE TESTING of B-MODE IMAGES

Quality assurance testing of diagnostic ultrasound equipment involves the periodic testing of the image quality by the sonographer. Such a program is of primary importance in obtaining consistent image quality with a minimum of scanning time. Recent surveys of B-scan equipment performance indicates that many diagnostic ultrasound systems in routine clinical use in some cases were performing below manufacturers specifications (28,29). In many cases, the sonographer is unaware of the deficiencies. This is unfortunate, because periodic testing of ultrasound scanning equipment can detect significant changes in system performance as they take place.

Seven basic parameters that affect B-mode images in diagnostic ultrasound that can easily be measured by a sonographer are:

1. Sensitivity
2. Lateral Resolution (Beam Width)
3. Range Resolution (Pulse Length)
4. Image Registration
5. Depth Calibration (Distance Measurements)
6. Dead Zone
7. Dynamic Range (Range of signals that can be detected and displayed)

Periodic evaluation of the equipment with regard to these parameters can help assure that the scan quality has remained consistent. The first six parameters can be measured using a standard AIUM test object (29), and for discussion purposes the use of the AIUM test object will be referred to. Figure 13 illustrates a side view of the AIUM test object and the rod spacing. Several techniques have been used for the measurement of the last parameter listed above i.e. the dynamic range of the system. Meaurement methods include (1) electronic pulse generator which emits a sequence of pulses decaying at a selectable rate; (2) a polyproponol wedge designed to attenuate acoustic echoes over a range from 0 to 60 dB; and (3) a series of stainless steel reflectors varying in angle from zero to 10 degrees so that the received echoes vary over a 40 dB range. One of the problems with the electronic test device is that it excludes the transducer when testing the dynamic range of the system. The use of all three methods has been described in the literature (30).

Diagram of the AIUM Standard 100 mm Test Object
(Dimensions are in millimeters)

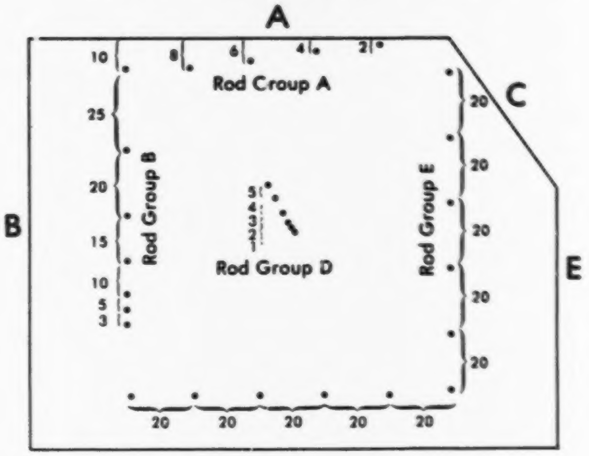


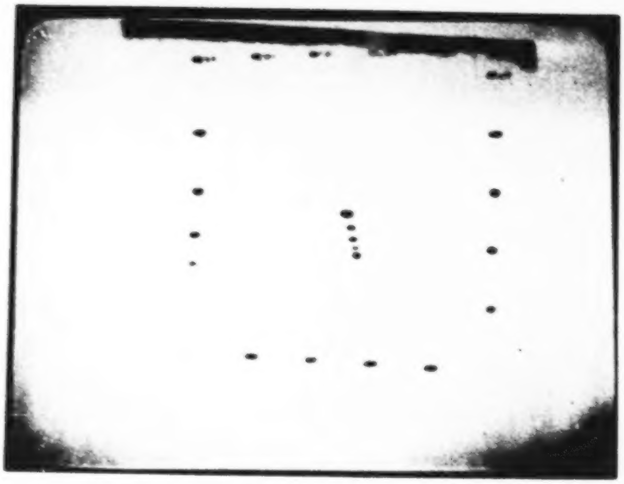
Figure 13

Sensitivity

The sensitivity of the receiver along with the frequency of the transducer determines the maximum penetration in a given clinical examination. The overall sensitivity of the receiver is specified in dB. The more sensitive the receiver (i.e., the higher amplifier gain) the greater the sensitivity of the system. The absorption of ultrasound per unit depth of tissue (which increases with frequency) deceases the depth at which imaging can be done for a given sensitivity. For imaging purposes it is important that the sensitivity be as high as possible and stable with time for a given transducer. Because of output differences from different transducers, and variation of penetration with frequency, the system performance will vary from one transducer to another. Thus, quality assurance testing should be done for each transducer used clinically. Variations of sensitivity of the B-scanner with time can be detected by measuring the gain settings required to obtain a reproducible echo from the bottom left hand rod in the AIUM test object (31). By keeping a record of this information as a function of time one can know if the sensitivity of a system changes in a way that decreases the imaging capability.

Lateral Resolution (Beam Width)

One of the limiting parameters with regard to the resolution in the image produced by an ultrasonic transducer system is the beam width i.e., the lateral resolution. This is illustrated when using of the AIUM test object since the reflections from the rods in the test object are displayed on the screen as lines when the transducer scans each rod as shown in Figure 14. The width of this line provides a measure of the beam width of the ultrasonic field. In order to obtain maximum resolution at a point of interest, diagnostic transducers are commonly focused to obtain a narrow beam width at a certain distance from the transducer face (generally 5 to 7 cm).



AIUM Test Object Image

Figure 14

Range Resolution (Pulse Length)

The range resolution of a transducer provides a measure of the pulse length. The range resolution is generally better than the lateral resolution and therefore is generally not a limiting parameter in a compound scan. However, in a single pass scan, the range resolution determines the resolution capabilities in the image. Use of the standard test object allows a numerical value to be obtained for the range resolution in millimeters. This is accomplished by imaging a set of reflectors with decreasing spacing. The smallest spacing which can be resolved between reflectors in the direction of propagation of the ultrasonic beam defines the range resolution of the transducer and the scanner. The range resolution also provides an indication of the integrity of the transducer. For example, if a transducer has been damaged, the range resolution of the transducer may decrease significantly. Routine checking of this parameter provides a quick and easy method of determining the integrity of the transducer.

Image Registration

In order that the position of the reflections from organs and other interfaces in the body be properly presented in the ultrasound image, proper registration of the received echos on the display is essential. If B-mode registration is not properly adjusted, the displayed position of a reflector at a given point in the body will depend upon the position and orientation of the transducer resulting in misrepresentation in the image. This will result in distortion and compound scans will suffer a blurring effect because the position of the same reflector will be displayed at different locations for each scan or different angulation. Registration of B-mode system can be easily checked by scanning a test object from different surfaces. Such scans should display the rods in the same location if the scanner is in correct B-mode alignment. Since the rods in the test object are visualized as lines, scanning each rod from a different angle should produce groups of intersecting lines if the B-mode registration is correct. If the B-mode scanner is out of alignment, the scanner rods from different angles will produce lines that either do not intersect at all or do not intersect at a point.

Depth Calibration (Distance Measurements)

In producing an ultrasound image that will be used for measuring structures within the body, it is essential that calibrated depth markers (distance measurement indications) be used. The depth marker dots establish a distance scale on the recorded image (usually at 1 cm apart). In actual practice, the depth marker dots should be placed along the line of measurement. When making distance measurements, these 1-cm depth marker dots can be used as reference. The accuracy of the spacing of the depth marker dots can be easily checked using a test object by imaging the set of rods in the test object that are placed at known distances apart. If in such a scan the image of the rods do not agree accurately with the electronic range markers, then (1) the system is not calibrated, or (2) the test object has not been filled with a correct water alcohol mixture to provide a propagation velocity equivalent to that of tissues (1540 m/s). This method can also be used as a procedure to evaluate the fluid in the test object if a unit with calibrated depth markers is used.

Dead Zone

The dead zone of the transducer is the region of the ultrasound scan where no object can be imaged. It usually appears as a dark area over the top of the scan. The width of this region indicates the space where the transducer will be "blind" to any object scanned. Using the AIUM test object, the dead zone can be determined by noting the distance between the top surface and the image of where the series of rods located close to the top of the test object can be resolved (see Figure 14).

Dynamic Range

The dynamic range of a receiver (amplifier) is defined as the ratio expressed in dB notation, between the largest detectable echo amplitude received and the smallest detectable echo amplitude and is a critical parameter in evaluating a receiver. It is important for a system to have a wide dynamic range since the echoes received from the patient can vary up to 120 dB in dynamic range. It has been recommended that useful echo information at a given depth should cover a dynamic range of approxiamtely 40 dB (the dynamic range of tissue reflection coefficient at that depth) (31). Thus the receiver should have approximately 40 dB of dynamic range at a given depth in a patient (i.e., a given fixed value of gain voltage). One of the things that can limit the maximum useful dynamic range in a clinical examination is the ultrasonic beam pattern. For example if a transducer has excessively strong side lobes, artifactual information may be included in the image, such as echos from the side lobes being reflected back to the transducer and erroneously placed in the image along the direction of propagation of the beam axis.

CONCLUSION

We have attempted to describe some of the procedures available for both measuring the output from diagnostic machines and determining the imaging capability of pulse echo diagnostic units. We have reviewed the output from typical diagnostic machines and compared these with biological effects data reported in the literature. In the use of diagnostic machines it is desirable to employ the lowest possible output level consistent with obtaining needed diagnostic imaging information. Routine testing of the imaging capability of the scanning system allows the sonographer to detect changes in the system performance before clinical diagnosis is severely affected.

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THE BRH PROPOSED ACTION PROGRAM for DIAGNOSTIC ULTRASOUND EQUIPMENT

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Director, Division of Compliance
Bureau of Radiological Health, FDA

I guess I am the Bureau anchorman today for diagnostic ultrasound. I want to tell you what we are currently doing under the Radiation Control Act and the Medical Device Amendments and what we are proposing to do as described in a Notice of Intent, published in the FEDERAL REGISTER on February 13, 1979.

First let us discuss this FEDERAL REGISTER publication. The Notice of Intent (Notice of Inquiry would probably be a better title) announces that the Food and Drug Administraton is considering an action program for all diagnostic ultrasound equipment. Possible future actions include recommended user procedures, recommended training criteria for users, regulations or recommendations for equipment performance, and informational requirements. Before these actions are taken, we want the opinions of the public, States and professionals, on what they believe to be the proper approach to assuring the safe and effective use of diagnositic ultrasound. However, we have not taken the trouble of publishing the NOI without having done homework. Much of that preliminary research you have already heard about from Dr. Stratmeyer and Dr. Stewart from the Bureau.

Before taking the first formal agency action of publishing the NOI, the Bureau consulted with its two advisory committees. Both the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) and the Medical Radiation Advisory Committee (MRAC) reviewed drafts for the NOI and generally supported its publication. Another FDA advisory committee, the Obstetrical and Gynecological Device Classification Panel recommended that all diagnostic ultrasound devices be classified in Class II, performance standards. This later action was taken under the Medical Device Amendments of 1976. I will talk more about the impact of the medical device regulation later.

Although the benefits of diagnostic ultrasound have been demonstrated in many fields of medicine, the possible risks of the modality are not fully understood. There have been no clinical reports of adverse effects, but such negative data do not conclusively establish the safety of diagnostic ultrasound. Also, there has not been any conclusive epidemiological evidence of the risks or safety of diagnostic ultrasound. We must, therefore, rely on animal studies as indicative of possible effects on humans. I will not attempt to review the present status of bioeffects research. Dr. Stratmeyer has ably covered that subject. There are two things we are quite sure about. One is that there is insufficient data at this time to establish safe exposure limits with great confidence. The other is that the clinical use of diagnostic ultrasound is expanding rapidly in many varied medical specialties. The Notice of Intent discusses these points more fully and concludes that manufacturers should not state in advertising and promotional literature that diagnostic ultrasound is unequivocally safe. Furthermore, in agreement with most professional organizations, it is not considered acceptable to expose pregnant women for commercial demonstration of equipment. On the clinical side, it seems prudent to use the lowest practical exposure levels, consistent with obtaining needed diagnostic information. Also, diagnostic ultrasound should not be used indiscriminately, but rather only when there is a valid medical reason. In other words, do not visualize the fetus just to amuse the mother. I do not know if anyone is doing that today, but it clearly is taking a possible risk with little, if any, benefit to the patient.

I would now like to discuss an important feature of the Notice of Intent, namely the questions and conceptual criteria for both users and manufacturers of diagnostic ultrasound equipment. The "conceptual criteria" are not intended as guidelines to be followed now, but merely as possible features of future voluntary or regulatory activities which are presented for comment.

For users, the questions and conceptual criteria are:

1. Diagnostic ultrasound should be used for human exposure only when there is a valid medical reason. Which of the following or what additional reasons should be considered valid (and under what conditions): medical diagnosis, patient or fetal monitoring, and educational and research applications approved by institutional review boards?

2. Users of diagnostic ultrasound equipment should have adequate training. How extensive should the training be? Should the training be only formalized training? Should it include instruction in both operator techniques and interpretation of diagnostic ultrasound information, instruction in performance measurements and procedures, and instruction in biological effects of ultrasound radiation?

3. Users of diagnostic ultrasound should implement adequate routine quality assurance programs to monitor equipment performance. What should be the elements of such programs? For example, should system sensitivity, depth calibration, and transducer resolution be periodically measured? What other measurements should be made?

We would appreciate any comments you have on these items, particularly if they are supported by data or other information. Any comments should be submitted as described in the NOI. The comment period ends on August 13, 1979, so you still have plenty of time.

For manufacturers of diagnostic ultrasound equipment, the questions and conceptual criteria are:

1. Manufacturers' specifications regarding ultrasound emissions, as well as imaging effectiveness, should be provided to the user. Which parameters should be specified? (E.G., maximum and average ultrasound intensity in time and space; maximum and average ultrasound power; transducer pulse shape, pulse duration, and pulse repetition rate.)

2. Manufacturers should adopt quality control and testing programs adequate to assure that equipment performance specifications are met and that information provided with equipment is accurate. What are the elements of an adequate testing program for the manufacture of diagnostic ultrasound equipment?

3. Ultrasonic equipment maximum output capabilities should be as low as practical, consistent with obtaining needed diagnostic information. Should there be a specific recommended or mandatory limit on equipment output? Would such a limit discourage trends to increase equipment output? Would such a limit be viewed as a "perfectly safe" level?

4. Diagnostic ultrasound should be used for human exposure only when there is a valid reason for its use. Are there any valid reasons for exposure of humans to diagnostic ultrasound for purposes of commercial demonstrations?

Again, we sincerely want your comments and supporting data.

I would like to mention that we recognize and encourage the voluntary standards setting efforts of industry and others. For example, there is a joint project by the National Electrical Manufacturers Association (NEMA) and the American Institute of Ultrasound in Medicine (AIUM) to develop a safety performance standard for diagnostic ultrasound equipment. We will consider the results of this and other voluntary efforts, if timely, before taking further action.

As I noted earlier, diagnostic ultrasound instruments are medical devices, subject to FDA's authority under the Medical Device Amendments of 1976. Of course, diagnostic ultrasound equipment is also subject to the Radiation Control for Health and Safety Act of 1968 (P.L. 90-602), the only authority that BRH has used to control such devices in the past.

Under the medical device legislation, diagnostic ultrasound has been proposed to be classified into Class II and probably will formally be so classified in the near future. Class II (performance standards) is one of the three possible classifications for medical devices. Class III, the most stringent control, would require premarket approval. Class I (general controls), the least restrictive class, involves such controls as establishment registration and listing of devices, requirements concerning good manufacturing practices (GMP's), and provisions on records and reports. It is important to keep in mind two facts about devices designated Class II. One is that a nonregulatory standard may be acceptable to FDA. For example, a standard developed by AIUM may be recognized by FDA if it is both adequate to insure safety and effectiveness, and it is adhered to by all manufacturers. Since there are approximately 2,000 under FDA's authority, the Agency wants to impose mandatory controls only where really necessary. Also, it is obvious that simply classifying a device into Class II does not mean standards development will start immediately. There are simply too many devices, priorities will have to be set and this has not been done yet.

Under the recent agreement between the Bureau of Radiological Health and the Bureau of Medical Devices, BRH will be the lead Bureau within FDA for most radiation-type medical devices, including diagnostic ultrasound. What the Radiation Control Act could not do for electronic products, that is total safety and efficacy, the Medical Device Amendments can. The combined authorities will fulfill a mission the Bureau has long desired, at least for electronic products that are medical devices.

Perhaps the most immediate impact on medical device manufacturers are the Good Manufacturing Practice Regulations that were effective last December. Factory GMP inspections will be performed every 2 years by FDA-GMP inspectors.

A mention should be made about ultrasound therapy equipment. I am sure most of you know that a standard for this equipment became effective this February. The ultrasound therapy devices, then, will have to meet the Radiation Control Act performance standard and also will be subject to all provisions of the Medical Device Amendments.

In conclusion, let me encourage you to participate in the development of the FDA program in diagnostic ultrasound at the initial stages. The best way to do this is to carefully read the Notice of Intent, and to give us your comments.

The ADMINISTRATION'S PLAN for RADIOACTIVE WASTE MANAGEMENT

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INTRODUCTION

Until quite recently, it would have been impossible to address the subject because there was no documented consensus within the Administration. The Interagency Review Group (IRG) has recently developed such a consensus on top level issues in nuclear waste management. The President is expected to announce the Administration's position on the report including open issues in the near future. I will summarize the results of the IRG effort, describe two issues on which the IRG developed options and on which the President may define the Administration's position, and address low level waste management as an example of what may happen next.

SUMMARY OF THE IRG REPORT

The IRG recognizes that many members of the public and industry feel a sense of urgency with respect to seeing the Government achieve concrete progress in the waste management program. This urgency cannot be ascribed to any imminent public danger from existing waste and spent fuel now stored at power reactors. However, there is a need to be assured that present waste management programs are proceeding in the proper direction and using the proper approaches to meet fundamental objectives. The IRG is therefore more concerned about good decision-making today than about past and high-visibility remains, and applies equally to all branches of Government. The needed care, however, does not preclude early decision-making or other early actions. The IRG is convinced that all of the recommendations that it has developed, or to which it is giving serious consideration, are fully compatible with these principles and should not prejudice the outcome of future NEPA reviews.

Major IRG recommendations and findings include:

1. objectives for waste management;
2. technical findings on the status of the mined repository approach for ultimate disposal of nuclear wastes;
3. key elements of an Interim Strategic Planning Basis for disposal of TRU and high-level waste;
4. establishment of a State Planning Council to address institutional issues including regional siting of facilities;
5. support of the consultation and concurrence process for joint planning with State and local governments;
6. establishment of lead DOE responsibility for overall waste management planning;
7. improved approach to dealing with regulatory issues including (1) expediting the timetable for developing standards and criteria and (2) formal coordination processes between EPA, NRC, DOT, and DOE;

8. licensing of all new ultimate waste disposal facilities; and

9. actions on storage of commercially-generated spent fuel.

OBJECTIVES

The IRG recommends that the primary objective of waste management planning and implementation be that: Existing and future nuclear waste from military and civilian activities (including discarded spent fuel from the once-through nuclear fuel cycle) should be isolated from the biosphere and post no significant threat to public health and safety.

Of the sub-objectives stated by the IRG, the following are most important:

1. The selected technical option must meet all of the relevant radiological protection criteria as well as any other applicable regulatory requirements; although zero release of radionuclides cannot be assured, any potential release of radionuclides should be within pre-established standards and, beyond that, be reduced to the lowest level practicable.

2. The paramount consideration must be the public health and safety. The program should explicitly include consideration of all aspects of the waste management system including safety, environmental, organizational, and institutional factors.

3. The responsibility for establishing a waste management program shall not be deferred to future generations. Moreover, the system should not depend on the long-term stability or operation of social or governmental institutions for the security of waste isolation after disposal.

4. The capability to deal with a wide range of alternative situations in the future must exist. The basic elements of the program should be independent of the size of the nuclear industry and of the resolution of specific fuel-cycle or reactor-design issues of the nuclear power industry.

5. Appropriate cost of storage and disposal of any waste generated in the private sector should be paid for by the generator and borne by the beneficiary.

TECHNICAL FINDINGS

The IRG review identified a number of important technical findings that it believes to represent the views of a majority of informed technical experts.

1. A systems approach should be used to select the geologic environment, repository site, and waste form.

2. Overall scientific and technological knowledge is adequate to proceed with region selection and site characterization, despite the limitations in our current knowledge and modeling capability.

3. Detailed studies of specific, potential repository sites in different geologic environments should begin immediately.

4. The actinide activity in TRU wastes and HLW suggest that both waste types present problems of comparable magnitude for the very long term (i.e., greater than 1,000 years).

5. The degree of long-term isolation provided by repository, viewed as a system, and the effects of changes in repository design, geology, climate, and human activities on the public health and safety can only be assessed through analytical modeling.

6. The effects of future human activity must be evaluated more carefully.

The IRG has clarified the detailed statement of its second technical as follows:

Present scientific and technological knowledge is adequate to identify potential repository sites for further investigation. No scientific or technical reason is known that would prevent identifying a site that is suitable for a repository provided that the systems view is utilized rigorously to evaluate the suitability of sites and designs, and in minimizing the influence of future human activities. A suitable site is one at which a repository would meet predetermined criteria and which would provide a high degree of assurance that radioactive waste can be successfully isolated from the biosphere for periods of thousands of years. For periods beyond a few thousand years, our capability to assess the performance of the repository diminishes and the degree of assurance is therefore reduced.

The feasibility of safety disposing of high level waste in mined repositories can only be assessed on the basis of specific investigations at and determinations of suitability of particular sites. Information obtained at each successive step of site selection and repository development will permit reevaluation of risks, uncertainties, and the ability of the site and repository to meet regulatory standards. Such reevaluations would lead either to abandonment of the site of a decision to proceed to the next step. Reliance on conservative engineering practices and multiple independent barriers can reduce some risks and compensate for some uncertainties. However, even at the time of decommissioning some uncertainty about repository performance will still exist. Thus, in addition to technical evaluation, a societal judgment that considers the level of risk and the associated uncertainty will be necessary.

KEY ELEMENTS OF INTERIM STRATEGIC PLANNING BASIS

The IRG has expanded and clarified its thoughts on the interim strategic planning basis for HLW. The following passages reflect this expanded deliberation:

1. The approach to permanent disposal of nuclear waste should proceed on a stepwise basis in a technically conservative manner.

2. After having examined the status of knowledge relevant to disposal in mined repositories and by such other technical options as placement in deep ocean sediments, placement in very deep drill holes, placement in a mined cavity in a manner that leads to rock melting, partitioning of reprocessing waste and transmutation of transuranic elements, and ejection into space, we conclude that near-term program activities should be predicated on the tentative assumption made for interim planning purposes that the first disposal facilities will be mined repositories. The nearer term alternative approaches (i.e., deep ocean sediments and very deep holes) should be given funding support so that they may be adequately evaluated as potential competitors. Funding of other concepts should allow some feasibility and preliminary design work to proceed. Once the NEPA process has been completed, program activities can be tailored accordingly.

3. A number of potential sites in a variety of geologic environments should be identified and early action should be taken to reserve the option to use them if needed at an appropriate time. In order to avoid working toward and ultimately having a single national repository, near-term options should create the option to have at least two (and possibly three) repositories become operational within this century, ideally and insofar as technical and other considerations permit, in

different regions of the country. In pursuing a regional approach to siting, geologic, hydrologic, tectronic, and other technical characteristics of sites and safety considerations must remain in the primary basis for selection.

4. Construction and operation of a repository should proceed on a stepwise basis and initial emplacement of waste in at least the first repository should be planned to proceed on a technically conservative basis and permit retrievability of the waste for some initial period of time. Further definition of the retrievability concept, the circumstances in which waste would be retrieved and the technical aspects (including development of waste packaging, containers, and handling) is necessary.

5. Interim storage of spent fuel is required during the period of time before disposal facilities are available and will reduce the heat burden for disposal. To the maximum extent possible, utilities should keep their spent fuel at reactors until a repository is available. However, some quantity of spent fuel will have to move to away-from-reactor storage. In order to assist in providing flexibility to the program for selecting repository sites and bringing repositories into operation, the Federal Government should provide storage capacity as needed for limited quantities of spent fuel. All costs of storage and disposal should be paid by the utilities.

6. An ISF is not an essential component of a program leading to a full-scale repository. Nonetheless, if an appropriate opportunity to build an ISF on a schedule significantly prior to the opening of the first full-scale, high-level waste repository, were to exist, the opportunity should be taken. From a purely technical perspective, an appropriate opportunity implies technical readiness and the completion of an adequate site characterization program. However, other nontechnical factors should also be taken into account. Some agencies believe that an adequate site characterization program must include characterization of a variety of sites, in different geologic environments and relying on diverse media. All ISF's should be licensed, since these elements will be an important step in the ultimate location and construction of repositories to acquire institutional experience and to protect public health and safety.

7. Near-term R&D and site characterization programs should be designed so that at the earliest date feasible, sites selected for location of a repository can be chosen from among a set with a variety of potential host rock and geohydrological characteristics. To accomplish this, R&D on several potential emplacement media and site characterization work on a variety of geologic environments should be increased promptly.

All IRG members agree with the above elements of the recommended interim strategic planning base for high-level waste. The elements

1. do not prejudge the NEPA process,
2. require the Federal Government to maintain a technically conservative approach,
3. call for resolution of uncertainties by increasing the technical and program breadth with respect to the near-term repository characterization program,
4. do not preclude subsequent adoption of longer term technologies inasmuch as they call for increased R&D to develop selected alternatives, and
5. support a step-wise approach to the development of a HEW repository, while maintaining storage capacity for managing waste until emplacement and disposal opportunities are available.

STATE PLANNING COUNCIL

The IRG feels that there is a special and very useful role for a body comprised of elected officials. At the same time there is also an important place for other advisory mechanisms comprised of technical experts, representatives of special interest, and members of the public. Such mechanisms are discussed in the section on public participation.

The IRG believes that the Council should be composed of elected officials appointed by the President and policy level representatives of the President. A Council of 18 members is proposed. The chairman of the Council would be a Governor appointed and designated by the President. The Council would report its findings and recommendations to the President, the Secretary of Energy, and the Congress.

The functions and responsibilities of the State Planning Council would not involve implementation responsibilities and would include the following:

1. Provide State perspectives for the development of the National Nuclear Waste Management Plan, the site characterization program and other waste activity planning, and other planning documents to ensure that they adequately address the needs of the States and localities.

2. Prepare an annual report on its activities to include its recommendations concerning the Government's nuclear waste disposal programs.

3. Advise on the regional distrification, characterization, and placement of facilities for the management and disposal of nuclear wastes and review and make recommendations regarding the process for selecting, characterizing, and determining the suitability of potential repository sites.

4. Assist DOE and the States in recommending proposed sites and licensing by NRC to assure that the needs of the States and localities are met.

5. Establish under its auspices such advisory committees as are deemed necessary to assist in its deliberations. Such committees should include representatives of all relevant interest groups.

6. Define additional State roles in the Federal Government's waste management program including State organizational and other institutional questions.

CONSULTATION AND CONCURRENCE

The IRG recognizes that there are several proponents of legislation for State veto of DOE waste management decisions within those States or perhaps any State. This view is a product of a number of factors, including the belief that wastes should not be disposed of in particular States and dissatisfaction with the United States Government's historical approach in dealing with State participation in the site identification and characterization process. The IRG does not believe that prior approaches to Federal/State relations have been practical and constructive or that provision of State veto by itself will necessarily result in constructive participation by the States in the development and implementation of the waste management program.

The IRG believes that the technical and socio-political success of any Federal waste management program is largely dependent on the States; and in particular the extent to which the States are involved early-on in program planning R&D, site identification, site characterization, development of regional programs to assess geologic formations using the sytems approach, and finally site selection. This should begin well in advance of the licensing and regulatory processes with participation early-on in DOE program planning.

Consultation and concurrence, by contrast, implies an ongoing dialogue participation and the development of a cooperative relationship between States and all relevant Federal agencies during program planning and the site identification and characterization programs on a regional basis using the systems approach, through the identification of specific sites, the joint decision on a facility, any subsequent licensing process and through the entire period of operation and decommissioning. Under this approach the State effectively has a continuing ability to participate in activities at all points throughout the course of the activity and, if it deems appropriate, to prevent the continuance of Federal activities. The IRG believes that such an approach will lead to better protection of the States' interests than would a system of State veto by which is usually meant that a State approves or disapproves of Federal activities at one specific moment, as well as ensure effective State participation in the Federal Government's waste management program. Such an approach will also lead to freer access to areas for the conduct of geologic investigations.

ISSUES THAT MAY BE DECIDED BY THE PRESIDENT

The IRG has defined four technical strategies for the development of a high level waste repository:

1. Strategy I provides that only mined repositories would be considered and that only geological environments with salt as the emplacement media would be considered for the first several repositories. As a result of past focusing on salt, there is a large volume of information available. In addition, one body of opinion holds that salt is the best, or at least an acceptable, emplacement medium and that suitable sites can be found where salt is the host rock.

2. Strategy II provides that, for the first few facilities, only mined repositories would be considered. A choice of site for the first repository would be made from among whatever types of environments have been adequately characterized at the time of choice. Because generic understanding of engineering features of a salt repository are most advanced, the first choice is expected to be made from environments based on salt geology. Sites from a wider range of geologic environments would be available for selection somewhat later.

3. Strategy III provides that, for the first facility only mined repositories would be considered. However, three to five geological environments possessing a wide variety of emplacement media would be examined before a selection was made. Other technological options would be contenders as soon as they had been shown to be technologically sound and economically feasible.

4. Strategy IV provides that the choice of technical options and, if appropriate, geological environment be made only after information about a number of environments and other technical options has been obtained.

These strategies were defined by the IRG Subgroups so as to illustrate particular characteristics of a range of possible strategic approaches. These were not intended to be a complete list of possible strategies or comprehensive descriptions of a strategic planning basis that might actually be adopted by the waste disposal program. For the latter purpose, they are admittedly incomplete.

It has been speculated that strategies III or II may be adopted by the Administration.

Another issue is the nature and location of the Waste Isolation Pilot Plant (WIPP) and its role in the permanent disposal of defense TRU wastes, with or without an "Intermediate Scale Facility" (ISF) for the permanent disposal of up to 1,000 spent fuel assemblies form commercial power reactors. The alternatives are described in the recently published draft Environmental Impact Statement on the WIPP:

1. No action. No ISF is built, and TRU waste remains stored at the Idaho National Engineering Laboratory and elsewhere as it is now.

2. The WIPP reference repository in southeastern New Mexico.

3. The WIPP reference repository, but without the ISF.

4. Disposal of TRU waste in the first available HEW repository. By 1982 or soon thereafter, sites in the Gulf interior region salt domes and Hanford basalt should be available for consideration. An HEW repository would be built at one such site, and TRU waste would be put into it. The initial retrievable-storage phase of the repository would take the place of the ISF.

5. Delay of the WIPP reference repository. By 1982 or so, the WIPP may also have the choice of dome salt and basalt sites.

6. Same, but without the ISF.

7. A longer delay. By 1985 or somewhat thereafter, sites may also be available in granite, tuff, or shale for an HLW repository.

LOW LEVEL WASTE

With only three sites accepting commercially generated low level waste in the country, there is little flexibility in this operational area that is of interest to many research organizations, hospitals, and the nuclear industry. The IRG has recommended that the Department of Energy develop a national plan for the disposal of all low level waste and do so with broad participation among interested parties; accelerate programs to improve shallow land burial and develop alternatives for shallow land burial as required; and give the States the option to retain management control over present commercial burial grounds or to transfer such control to the Federal Government.

In response, the Department will develop a draft "national stragety document" in consultation with organizations such as the National Governors Association, this Conference, and other interested parties. The Idaho Operations Office as the Department's lead organization for low level waste will contact the Conference about this document. Our tentative schedule calls for;

1. a stragegy outline by July 1979,

2. drafts of chapters by October 1979,

3. review (outside DOE) until January 1980,

4. issue for public comment May 1980,

5. receive public comment until December 1980, and

6. issue Version 1 of the document June 1981.

We hope to begin receiving your input at an early stage, such as on the outline of the document, to assure that the product factors in your interests and concerns.

DISCUSSION

MR. NEILL: You mentioned a number of actions that need to be taken to work together with the States in development of strategies for waste management. You cited this a number of times. Could you speculate on why the States were deleted from the list of organizations in preparation of the IRG?

DR. OERTEL: What do you mean deleted from the list of organizations?

MR. NEILL: Well, the 14 Federal agencies sat down to develop a strategy, a plan of action, to identify the work that needs to be done in the area of waste management. It is limited to a list of Federal agencies.

DR. OERTEL: The answer here is that if you want to go to the public with something that supposedly represents the Federal Government's position, you have to get your own house in order first. The first step was to bring the Federal agencies together. The idea was not to exclude others, but to put one's own house in order first.

MR. NEILL: I misunderstood. I thought you were describing a national plan, not a Federal plan.

DR. OERTEL: You are quite right. The national plan is more than the Federal plan. As soon as there is a Federal plan, it becomes possible to go into a national phase. And that is precisely what we expect to go with. The contacts have been made. There was a meeting with Governor Evans of Idaho, who chairs the Radioactive Waste Management Group for the National Governors Association. That was held in Denver last month and was the first step. The next step will be the establishment of a State Planning Council, probably in association with the National Governors Association.

STATE RESPONSE to the FEDERAL PROGRAM for RADIOACTIVE WASTE MANAGEMENT

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We in the Conference of Radiation Control Directors recognize that there currently exists substantial nuclear waste, primarily as a result of defense activities, and to a lesser extent, from the commercial area. Because of the many beneficial uses of various radioactive materials, additional radioactive waste will be generated. As the individuals within the States that have the primary responsibility for radiation public health and safety, we strongly support the efforts of the Interagency Review Group (IRG) to develop a national radioactive waste management program with recommendations to the President on the establishment of an Administrative policy on the very vital matter.

A national policy on nuclear waste management is critically needed, and it is very unfortunate that it has taken so long to develop and implement. The Conference recognized this need over 7 years ago. I would like to quote from a report of our 1972 meeting. The Conference Workshop Report on Radioactive Waste Disposal stated: "The members of this workshop recognize the disposal of radioactive waste as being one of the more serious issues facing both the nuclear industry and State and Federal regulatory agencies." The report further stated, "There is insufficient State involvement in the decisions concerning disposal of radioactive waste," and recommended that, "The Conference urge the development of a national plan and policy on the management of radioactive waste and that the development of such be done with Conference participation."

We therefore commend the IRG for its recommendations and strongly urge that a vigorous national waste management program move forward.

Since the IRG Report is substantial in size and covers many complex issues, I have chosen to limit my comments primarily to the section on "Institutional Issues." I am sure this is the section of most concern to the States, as shown by the discussion on the IRG recommendations at the Nuclear Waste Management Workshop sponsored by the National Governor's Association, which was held just 2 weeks ago in Denver. Specifically, at this meeting, the participants concentrated almost entirely on the role of State and local governments in the nuclear waste management process, with particular emphasis on the concept, function, and purpose of the recommended State Planning Council and the meaning of the terms "consultation and concurrence."

This concern relative to the importance of a State role in the nuclear waste management program was stated in our chairwoman's letter of November 28 to the IRG. Her statement relates to the IRG recommendation of "..... a genuine and effective partnership of cooperative Federalism should be initiated between the States and the Federal government." In relation to this IRG recommendation, she stated, "Given the essence of the issue, it can only logically be concluded that some mechanism be developed that in fact assures a process of consultation, concurrence, and cooperation.

The importance of State participation in the nuclear waste management program is very actively being considered by the Congress. I am aware of 13 different bills relating to nuclear waste management that have been introduced in the Congress. There are probably others of which I am not aware. Of these 13 pieces of proposed legislation, at least 6 address the importance of State involvement in one manner or another. I would like to identify a few of these bills and their concern for State involvement.

1. Senate Bill 535, cited as the "Nuclear Waste Transportation Safety Act of 1979," would require DOT to develop a national emergency response plan to deal with emergency situations that may occur during the shipment of nuclear waste, commercial spent fuel, or other radioactive material, and states: "In developing the emergency response plan, the Secretary of DOT shall consult with those states and local governments....." which will be affected.

2. Senate Bill 701, cited as the"Radioactive Waste Management Act of 1979," would require that the Secretary of Energy notify any State of any investigation of any site in such State for the construction of any radioactive waste storage facility and allow such State to prevent the construction of such facility by action of State legislation or a Statewide referendum.

3. Senate Bill 742, cited as the "Nuclear Waste Management Reorganization Act of 1979," would require the establishment of a Nuclear Waste Planning Council to include representation by State, local and private citizens, which would serve in an advisory capacity to Federal agencies. This Bill also has other sections relating to State participation.

4. House Bill 1852, cited as the "Nuclear Waste Management Research, Development and Demonstration Act of 1979," would require DOE to notify the Governor of a waste repository site in his State, and if not agreed to by the Governor, DOE may not take action until the matter is resolved, or the Secretary finds the repository site is:

   a. consistent with public health and welfare and,

   b. would further the public interest with consideration to regional, State, and local interests.

There are others, such as Senate Bill 594, which would provide a formal process of State participation and concurrence regarding the management and storage of radioactive materials, House Bill 3302, requiring Federal and State coordination.

In addition to the interest in Congress for State involvement in radioactive waste management, I think we are all aware of the many State legislatures that are expressing themselves on the subject. I am aware of 15 States that have laws which either directly prohibit the establishment of radioactive waste sites, or require legislative approval for such sites. In addition, there are five other States with pending legislation that would either ban or require special legislative approval of such sites.

Why all this activity regarding State and local involvement in the nuclear waste management problem?

WITHOUT STATE AND LOCAL INVOLVEMENT AT A VERY EARLY STATE IN THE NATIONAL PROGRAM, IT IS DOOMED TO FAIL.

Yes, there is always the Federal "preemptive authority" but we do not believe such action is appropriate, nor do we believe this is the desire of the Congress and the present administration.

The need for an aggressive national program to manage nuclear waste exists now, and cannot be further delayed by court actions that would assuredly occur if Federal preemption were involved. Therefore, it is in the best interest of our country to rapidly move forward on this issue, and that I believe can most effectively be accomplished as recommended in the report, through cooperation between the States and Federal government, and this cooperation can best be achieved through a clearly understood "consultation and concurrence" concept between the Federal, State, and local governments.

The IRG report recommends the establishment of a "State Planning Council," whose purpose is to:

1. "Provide State perspectives for the development of the National Nuclear Waste Management Plan....."
2. "Prepare an annual report....to include its recommendations concerning the government's nuclear waste disposal programs"
3. "Advise on the regional distribution, characterization, and placement of facilities.... review and make recommendations regarding the process for selecting, characterizing and determining the suitability of potential repository sites."
4. And other functions of providing advice.

The IRG further recommends that this State Planning Council should be composed of State and local elected officials appointed by the President, and suggests the membership should consist of selected governors, Indian Nation representatives, officials of national organizations of State and local governments, and representatives of DOE and other Federal agencies.

I believe the members of this Conference would support this executive type State Planning Council to be the primary mechanism for State and local "input" into the nuclear waste management program. I further believe that should such an executive council be created that various State and local subgroups or task forces will be imperative to provide technical, economic, and environmental advice to the executive members. This Conference represents those persons in State and local governments who have the day-to-day responsibility to provide radiation protection for our citizens and have had a continuing task force on addressing problems in nuclear waste management since 1972. We, therefore strongly feel that this Conference should have appropriate representation and participation with the proposed executive planning council. This may best be done through the establishment of a permanent standing subcommittee on "Radiation Protection," whose membership is composed primarily by members of this Conference, appointed by the chairperson of the Conference.

It appears that the proposed State Planning Council would be primarily, if not entirely, providing recommendatons and advice to DOE. There are many other Federal agencies that are involved with the management of nuclear waste in which a formal mechanism for obtaining State and local recommendations would be desirable. Specifically, a very major concern relative to the nuclear waste management program is the transportation issue. It is likely that only a few States will be directly affected by site proposals. However, many, if not all, States will be impacted by the transport of spent fuel elements and/or nuclear waste, when the proposed nuclear waste program is fully implemented. Therefore, the concerns of the various States and local governments on the transport of these radioactive materials must be recognized at the Federal level of responsibility; primarily of DOT.

Likewise, we recognize the regulatory responsibility of the NRC in licensing sites and the EPA is setting criteria for such sites, and feel a formalized mechanism to recognize the State and local concerns on nuclear waste management by these agencies should be considered. I realize these agencies are regulatory in nature and have statutes to "carry out," but many of their decisions will impact the States and local governments. If the proposed "State Planning Council" is created, consideration should be given by these other Federal agencies to formally recognize this Council as a State and local advisory Council on nuclear waste management, and seek their advice on appropriate issues during their regulation proposals.

There were questions raised on the original draft report relative to what authority the Council would have. The final draft failed to respond to this question. If the State Planning Council is created, its authority must be clearly defined. It appears from the Report that the intent is that this Council will be advisory in nature. Assuming that its authority is only advisory, consideration should be given to the Council initially being created by Executive Order, then reinforced by subsequent legislation. Under the formal recognition by both the Administrative and Legislative branches of Government, advice and recommendations that are not adopted by the Federal agencies should be transmitted to Congress and the President for review and action.

I would now like to speak to the concept of "consultation and concurrence." There was considerable comment on the original draft indicating the need to better define what these terms meant. In response to these comments, the final IRG Report indicated that "consultation and concurrence" implies an ongoing dialogue participation and the development of a cooperative relationship among States and all relevant Federal agencies during program planning and the site identification and characterization programs; the joint decision on a facility. The report further defines this concept to mean "if it (State) deems appropriate to prevent the continuance of Federal activities."

In various discussions on the concept of "consultation and concurrence" two separate categories of States have been identified, potential host States for repository disposal sites, and interested States, defined as any State not being seriously considered as a potential host State. The concept of "consultation and concurrence" appears to be primarily applicable to potential host States, rather than interested States and in my opinion, is where the concept should apply. However, non-host States may be significantly impacted by a site in an adjoining host State. For example, a proposed site may be located on the border of a host State and close enough to an adjoining State to have a potential environmental impact. Additionally, several adjoining States may be significantly impacted by the transportation of spent fuel elements or nuclear waste by the location of a site in an adjoining or nearby host State. Therefore, although "consultation and concurrence" should primarily be directed to potential host States, those States immmediately adjacent to the host State, in which there exists potential for environmental impact, and those States significantly impacted by the transport of radioactive materials should be considered in "consultation and concurrence" process.

Questions have also been raised as to the role of the proposed State Planning Council on the concept of "consultation and concurrence." It appears inappropriate and unacceptable for such a Council to concur or not concur on individual specific sites. This should, and in most cases legally must, remain with the specific host State. However, it would not seem inappropriate for the Council to develop broad guidelines and criteria to be used in the process of consultation and concurrence, nor would it seem inappropriate for the Council to serve as a "sounding board" and possibly arbitrate for those areas in which site specific concurrence cannot be obtained. This does not imply nor am I suggesting that the Council should have authority to overrule the nonconcurrence by an individual host State. In fact, I believe legally, with the exception of Federal preemption, the individual host State must have the final concurrence decision.

The emphasis of the IRG report is on spent fuel, high-level waste, and transuranics, although low-level waste is addressed. Although the potential public health risks for low-level waste are not as great as high-level waste and spent fuel elements, some of the practicable problems may be greater for low-level waste simply because of the volume generated. I urge that a program for the management of low-level waste move forward with equal intensity as in the high-level waste area. In some instances, at least in some of those States with existing low-level waste sites, the problem is greater than the high-level waste problem. This is obviously one of perception and priority, but to some of those States with existing sites, it is a real and existing concern.

I believe the Conference would strongly support the IRG recommendation which states: "... that states be provided the option to retain management control of existing commercial sites or to transfer such control to the Federal Government."

The IRG was asked to further clarify the term "management control" in the above recommendation. The IRG's response was that the transfer of management control meant ".... that all responsibilities for care and inspection, all liabilities, leasing authorities and land ownership would revert to the Federal government." In this context, the report further states: "....in this area, the Federal government would, of course, work in close consultation with the States."

For those States interested in transferring "management control," I believe the precise meaning as indicated above, would be the desired meaning. On the other hand, I think tied to that meaning, must also be the concept of "consultation and concurrence" with the affected State for any proposed changed in use of a transferred site.

My last comments relate to the transportation of nuclear wastes. I have already spoken to the importance of the transportation issue to the States, and in fact, the IRG report states: "..... the transportation will be the primary topic in discussions with States and therefore certainly included in the consultation and concurrence process."

It is my personal belief, when the nuclear waste management issues are put into total perspective, there is a higher potential for public radiation exposure from the transport of the spent fuel elements and nuclear waste, than from the proposed storage and/or disposal of the material. I think I have some real support in this opinion if we look at some of the recent rail accidents involving other toxic materials. I realize that shipping casks for spent fuel elements have passed some very tough tests, but there are many different things that can happen in transportation accident. In fact, as stated in the IRG report, ".... the railroad industry has declined to accept the test results as conclusive evidence of cask integrity in accident condition, believing that scientific test criteria were not met." As stated previously, although only a few States are likely candidates for the location of a repository site, many, if not all, will have some type of waste transported in their State.

Because of this transportation concern by many States, it appears to me that a complete risk accident tree analysis study of potential transportation accidents is needed similar to the Rassmussen study of light water reactors.

In summary, because of the existing radioactive waste, and the anticipated future waste, an aggressive effort to establish a national nuclear waste program and direction is critically needed. Such a national program can only be effective with the cooperation of the State and local governments. We therefore commend the IRG for its efforts in this area, and feel the recommendations in general should provide the stimulus for establishing a national program.

Representing those persons who are involved on the "firing line," on a day-to-day basis of the protecting public from radiation exposure, we strongly urge Conference input relative to the decisions relating to a national nuclear waste program.

PANEL on STATE NOTIFICATION

E. Frank Wilson, Director
Bureau of Environmental Services
Arkansas Department of Health
and
Aubrey Godwin, Director
Division of Radiological Health
Alabama Department of Public Health

MR. WILSON: The Arkansas Legislature has passed Act 421 known as "The Hazardous Materials Act of 1977" which is "an act to regulate the labeling of containers of hazardous materials which are transported within this State and the adequacy of said containers; to require provision of adequate emergency equipment; to require prompt notification of public authorities of escape of such materials; and for other purposes."

This act was but a first step in regulating hazardous materials. It is clearly the intent of section 3 and 4 of Act 421 that the necessary steps be taken to reach the ultimate goal of establishing a system by which hazardous materials could be transported across, through, and within the State with the least possible danger to the citizens of the State, their property, and to the environment.

The State of Arkansas adopted the regulations of the United States Department of Transportation, Bureau of Material Transportation, hazardous materials regulations, as provided in Title 49, parts 100 through 199 of the Code of Federal Regulations, as amended.

The adoption of these regulations put into effect standards for containers to be used in the transportation of hazardous materials and requirements for placarding of vehicles transporting such materials. Adoption of the Department of Transportaton Regulations is not, however, a complete solution to the problem. Under sections 3 and 4 the mechanism is available for promulgating rules and regulations for prior notification of shipments of hazardous materials, use of escort vehicles, or other alternative rules or regulations. Section 6(e) makes it a criminal offense in the State of Arkansas for a carrier or transporter to fail to notify the proper authorities (which means the Arkansas State Police or the Office of Emergency Services, which may be reached 24 hours a day) of any spill or release of any hazardous material into the environment.

I am attempting to provide background information on which I may key my position concerning industry reporting requirements of hazardous materials. Act 421 provides most of the area I will be covering, however, I shall mention two other acts signed into law this year.

Act 651 which is "An act to require certain procedures to be followed by railroads transporting hazardous materials; and for other purposes."

Act 406 known as the "Arkansas Hazardous Waste Management Act of 1979." This is "An act relating to hazardous waste disposal: defining terms; empowering the Department of Pollution Control and Ecology to administer and enforce the Act and to adopt rules and regulations; outlining the powers and duties of the Department; requiring permits; providing remedies and prescribing penalties for violations; providing for severability; declaring an emergency; and for other purposes."

Normally when the average person thinks of hazardous materials today he thinks in terms of the most recent highly publicized news releases and published information on the subject. We here have all heard of Love Canal, waste contamination of areas near chemical landfills, and of course Metropolitan Edison Company's Three Mile Island complex in Pennsylvania where failure of some of the safeguards at that facility caused evacuation of a large number of people.

My remarks today will be limited to the hazardous materials pertaining to radioactive materials, nuclear fuels, radioactive wastes, and spent fuels, although I find it hard to distinguish between these and other hazardous materials.

All forms of government, local, State, and Federal, are taking a second look at ways of preventing and regulation hazardous materials. All facets are being reexamined and at this time it would be very easy for regulatory groups to react or overreact--with environmental lists, political, and social groups applying pressure. Because the energy needs of our country are growing and the energy companies need every break they can get, it seems they do not need to be overregulated at this time.

Nuclear fuels and waste hazards have been noted and regulated almost from the beginning; therefore, we find in the U.S. Department of Transportation Regulations requirements are quite specifically spelled out for reporting, labeling, shipping, and containerization or packaging ot radioactive materials.

In my opinion, it would be very easy for Arkansas, or individual States, to overreact and promulgate laws that would be impossible for most States to regulate or have the finances to implement. Many areas of regulations could easily conflict with other regulations and while these are being resolved, studied, and ruled on, it could very well hinder the implementation of very necessary regulations.

In a prepared speech presented in Arkansas on December 15, 1977, to the Arkansas Transportation Commission, Mr. Roy Garrison from the Washington Office, Mr. L.L. Turner from the Savannah River Project, and Mr. John Lamb from the Washington Office of the U.S. Department of Energy pointed out a few things I would like to reiterate here. Mr. Garrison stated that the nuclear fuel shipment casks cost about $2 or $3 million each, and to test these to destruction to verify or validate engineering design calculations would be extremely costly. Most States could ill afford testing on this scale so the Department of Energy Transport, Research, and Development Program, might best be the one to test, and should have the qualified personnel to handle the job. Mr. Garrison also stated, "The Department of Energy is now, and probably for the future will be, the largest or one of the largest shippers for the Government of nuclear energy materials. At the same time, of course, our activities are for and on behalf of the nation's taxpayers and citizens, and under continuous scrutiny by Congress." Mr. Garrison at this time quoted for the record: "For the record here today, I have a statement and this concerns the types and numbers of nuclear shipments, how nuclear shipments differ from other routine commerce, a theory of nuclear shipment safety, the Federal regulations, packaging integrity and packaging methods. Department of Energy Shipment policy; we make it a policy to follow all the Federal standards, and the Department of Energy Transport, Research and Development Program." Films were shown regarding testing, and regulations were briefly reviewed by the representatives of the Department of Energy. Problems were defined and spelled out and Mr. Linwood L. Turner, Chief, Transportation Branch, Savannah River Operations, U.S. Department of Energy states in regard to State Regulations versus Federal Regulations stated: "Inconsistencies arise, violations are caused by the very nature of the differences in regulations, instead of preventing them, because you have a standard approach. It causes confusion for enforcement, the DOT regulations say one thing, the State regulations may say something else. The carriers are looking at the Federal regulations and they're not really aware of all the State regulations. Also, finally and essentially, if State law is contrary to the intent of the Federal law does not meet the commerce, it may be illegal." I would like to point out that if I were a carrier and there were a conflict between the State Regulation and the Federal Regulation I would be obliged to either stop right there, or I would choose to meet the Federal Regulation first.

The very sincere concern of the people within our individual States about the increasing incidents involving hazardous materials has pointed out the need for regulations and controls. Some hazardous materials have been recognized for their hazards almost from the beginning, as is the case with nuclear materials, while other hazardous materials have been utilized at home, in industry, and in schools for a number of years and have gained widespread use and application. The very fact that the hazard was not recognized because of its insidious nature and the very long period of time before the hazard manifests itself, as in the case of asbestos fibers, we have a tendency to panic and overnight we feel something must be done immediately - and we are engulfed with a tremendous and almost overwhelming job. Much has been done, much must be done, and much is being done to alleviate the problems in as systematic a manner as possible. Just as any huge edifice cannot be constructed in a day, or a week, or a month - neither can it be taken apart piece by piece in a day, or a week, or a month. We have created problems over a long period of time--we now realize this and we have to do something about it. We are beginning to correct the problem and we must continue in the direction we have started--it will take time! Panic never solves a problem, but merely confuses the issue. My entire point here is: (1) We have identified or are identifying the problem or problem areas, (2) we are systematically attempting to eliminate or correct the problems utilizing available resources, and (3) it will take time. If each individual, town, city, county, and State panics and each implements the solution as he sees it, confusion and misdirection will be the result and little will ever be accomplished. To solve the existing problems will take a concerted team effort and eventually the problem can be solved.

One large trucking company stated that the implementation of rules and regulations initiated a few years back (where a number of changes were implemented concerning labeling) cost his company an estimated $200,000 annually. You and I, and every individual consumer pay this cost.

At this time, I would like to take a close look at a single proposal that is being considered in the State of Arkansas (under Act 421) for promulgation of regulations pertaining to the movement of nuclear fuels and nuclear waste requiring notification and clearance of routing prior to movement on the highways of Arkansas. Consideration will be given to requirements for escort vehicles during inclement weather and other times as determined by the Arkansas Transportation Commission.

First, I would like to consider prior notification of intent to ship a radioactive material. This would probably involve issuing permits to 80 percent of all trucking companies located in the midwest and south-central portion of the United States, at least, and many carriers outside these areas.

Arkansas can regulate all intrastate shipments of carriers domiciled within its boundaries and transported within the State. This constitutes no great problem. Once a carrier crosses a State line he is subject to Federal Regulations as well as State Regulations. This becomes a problem because of possible conflicts between State and Federal Regulations. Carriers based in other States that transport radioactive materials in and across the State that are domiciled in another State would make it difficult (if not impossible) to regulate by State Imposed Regulations. Arkansas is located geographically so that much of the traffic flow from east to west and north to south traverses the State. One example: A shipment from the northern tier of Atlantic Coast states consisting of nuclear fuel bound for California might very well pass through Arkansas. A carrier might use the northern route under normal conditions or during the summer months, but in midwinter would be forced by weather conditions to seek the more practical southern route. Regulations requiring prior notification by all shippers in and through Arkansas would tend to increase the cost, eventually passed on to the consumer and taxpayer. To implement such a program would be a tremendous cost to the State initially, and a burden to bear administratively through the years.

The second thing to look at would be clearance before shipping and routing. A carrier is provided a permit, clearance granted for the type load, and a route he must travel is selected. He is then ready to start. One might argue that this shouldn't present a problem, for the routes are prearranged, the permit is prearranged--so what's the problem? Five minutes or less by phone or teletype is all it takes. If the carrier has a partial load and must stop three times in the State, it would present a problem for the stop would not all be on this route or the carrier might need to leave the radioactive material at a terminal for transfer to another carrier. Road conditions might necessitate a change in route. Flash flooding in an area might make changes mandatory, or icing conditions, or a tornado, or even a mass demonstration against truckers or railroad shippers, or any number of reasons we haven't thought of yet. There would be a tremendous burden placed on the State again to maintain and implement a program staffed 24 hours a day and 365 days a year. To be efficient and to do the job properly, it would require this type of operation.

The third thing we need to look at would be a prearranged escort from the State line to the carrier's destination--again a 24-hour-a-day job, 365 days a year. To ensure a smooth flow of traffic, even under severe conditions of weather or whatever the communications required--the staff, the cars, and equipment (all combined) would be a staggering cost to the State and I fear the returns would be very meager indeed.

In closing, I would like to say that the State of Arkansas has reponded to 114 transportation incidents in the past 3 years, 1976 through 1978, and only 3 have involved radioactive materials, all of which were released to continue to their destination after proper evaluation and monitoring. One train wreck has cost in excess of $3 million in damage and cleanup operations to date; the the total cost is not yet available. Another transportation incident cost over $35,000 just to restock the fish killed as a result of the spill. It seems to me that the transportation of radioactive materials has a far better track record than for other types of hazardous materials such as poisons, insecticides, pesticides, rodenticides, fertilizers, herbicides, and other hazardous chemicals.

The State of Arkansas is in Region II of the DOE Radiological Assistance. Oak Ridge is the point of contact. I have a phone number that can be called and, if necessary, a team can respond immediately upon my request to any type of incident involving radioactive materials. Someone is available with help or assistance 24 hours a day--Saturdays, Sundays, and holidays included.

I, personally, wish to take a stand concerning Industry Requirements of Reporting Interstate and Intrastate Transportation of Hazardous Materials. I think the Federal Regulations are adequate. They have the backing of Congress and that backing will extend to the States, if adopted by the State, where implementation and enforcement is necessary. Congress, the Department of Transportaiton, the Department of Energy, the Nuclear Regulatory Commission, Materials Transportation Bureau, and others, are constantly updating and upgrading necessary requirements to protect the citizens, property, and environment. It is my sincere belief that the individual States could best serve themselves by establishing a reporting system and using their resources to see that the present Federal regulations are enforced--being sure all of the "i's" are dotted and all of the "t's" are crossed so that a smooth and orderly flow of materials may be maintained; establishing penalties if necessary to assure reporting; and seeing that no hazardous materials are dumped within their boundaries, as happened in North Carolina where waste oil containing PCB's were disposed of illegally beside the highways. I would recommend that the States utilize their resources to put qualified people in the field to see that these laws are fully implemented in the most practical way.

MR. GODWIN: I think you stole my talk, Frank. I was asked to talk about notification and requiring notification of shipments. Looking into the situation, I do not think anyone really wanting notification of the nuclear medicine shipments, that go through the State. It seems to me that we are primarily interested in major shipments of radioactive materials, or waste. If we are really interested in protecting the people, we ought to be interested in the large chemical shipments. That is where the real potential for injury to the public lies.

If we are going to go into such a system, we should approach it as an overall hazardous material shipment, as I believe Arkansas is approaching it, as opposed to radioactive material. Mention was made of inspections. I agree, we need to inspect them and we have an agreement with the Motor Carrier Bureau where we can go in and make inspections of interstate shipments and under our own regulations we can inspect intrastate shipments. If we find an interstate shipment that has a problem we would notify the local representative in the Motor Carrier Bureau and he in turn will take the necessary compliance action. If it is intrastate, we handle that on our own. It is primarily an inspection of our licensees. This is where it is a good point to inspect the shipments. The reasons for notification I think fall into two major categories.

You can advise the shipper of unique situations within your State. For instance, if you have flooding, tornadoes, you do get an opportunity to advise that individual that indeed such conditions exist and he can indeed reroute or hold up the shipment long enough to wait for these conditions to abate. I think that this is important because many times during shipments, controlling and scheduling of the shipments are in other States, well away from where you are.

Probably of more importance to us is that if it is going to require some of your less used instrumentation, you might want to make sure that the batteries are in fact usable and the equipment can work. On occasions when we have to consider other things, for example there have been cases where shipments were shot at (the problem with the vandalism). At least you would want your public safety people to be aware of this so that the security that is necessary for shipment can be provided.

Speaking of security, all these notification schemes do suffer, in that if you start notifying everybody throughout the State of your shipments, you probably will have an opportunity for someone to use that information to harrass the shipments. I do not have an easy answer. On the one hand the public is demanding that we know, on the other hand there is inducement for indiscriminate distribution of information.

DISCUSSION

DR. MILLS: This morning, Chuck Hardin called for a Rasmussen-type study for transportation offices. I have some reservations about that probabilistic kind of study of transportation, particularly in view of the fact that you and Frank both seem to be saying that the Federal regulations that are rewritten are satisfactory. Now did I miss something with respect to Chuck asking for a Rasmussen-type study?

MR. WILSON: Today is today, and I do not know what is going to happen 5 years from now. I cannot answer this for Chuck, but my own personal feeling is that we think the system we have now is all right, we just lack the manpower to really see that it runs. I think this is the big problem. In my State we have one DOT man to cover the entire State, so our Department of Transportation has about 12 or 15 people working 24 hours each a day, 7 days per week, and it seems quite obvious that there is no way they can do much about this. And they tell us that about every third shipment now, on our highway in Arkansas, and I am sure this is a pretty good rule of thumb, is a hazardous material shipment of some kind.

DR. MILLS: What I was concerned about is that probabilistic studies have always been inconclusive and therefore we will not be in any better position to make a decision.

MR. WILSON: I think that the answer in most cases is that the contamination is proper for the load. If you have a good container and it can withstand the normal impact, we are much better off. The human factor is the big problem.

MR. TEDFORD: The point I would like to make, based on what you have said and what we have experienced in Georgia, is that transportation accidents that have involved radioisotopes have been in the minority of incidents. I think in all the Agreement States, there have been 70 or 80 accidents in the last year; emergency response type accidents. Only one or two of those have involved transportation-type situations. The majority have been lost isotopes, spills, and so forth. So I just want to make this point in context and see if this was generally agreed upon.

DR. PARROTT: The thing that we are facing right now is you mentioned that you have one inspector for your State; we have one for the Northwest. He could care less about radioactive materials because his concern is pesticides; his concern is chlorine. Our legislatures are concerned about radioactive shipments and they could care less about the other ones, even though it was explained abundently clear in testimony that was presented before the Transportation Committee of the State of Oregon. Consequently, we have a bill that requires all kinds of things including permitting, and for essentially all shipments. What I am saying is that this is a political thing. We will have to face it, we will live up to whatever they say. I trust that we will be funded adequately to do it. I know better than this.

MR. GODWIN: Almost everybody is keeping up on the truck transportation. When we get into spent fuel shipments you best start looking at rail shipments, too. I do not have the same ability to work with rail shipments as I do with truck shipments. I can inspect truck shipments but we do not have an agreement with DOT to inspect rail shipments and I have not figured out how to work that out yet.

FEDERAL-STATE RELATIONS in the TRANSPORTATION of RADIOACTIVE MATERIALS

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

Today, I would like to touch on the general picture of the regulation seeking to achieve a safety record in the transportation of hazardous materials overall with particular respect to the radioactive materials side of the house. From our perspective at the Materials Transportation Bureau, where we have the responsibility for formulating and issuing the Federal Transportation Safety Standards, and to a certain extent, participating in the monitoring of those standards, we are convinced that an overall hazardous materials safety program depends upon five basic elements; (1) sound standards for the containment and handling of the material, (2) training of personnel involved in the shipment and the transport of that material, (3) monitoring, (4) emergency response capability, and (5) some form of review and analysis of the other four with feedback into them.

If I were required to put out a report card on the performance of my organization, the Materials Transportation Bureau, in the field of radioactive materials, in each of these five areas, I think I would probably assign a B+ for the standards for containment and handling, a D-with respect to training of personnel involved in the handling of it, an F in monitoring, a D-in emergency response, and probably a D- in review and analysis. I hope I am not anticipating the GAO representative too much by giving his report in advance.

Having made these observations about my own performance, what is happening in these areas? What is it that is being done or anticipated by my Agency in these five areas? First of all, in the area of sound standards for containment and handling, as you have heard the previous speakers talk about States adopting Federal standards, we are encouraging, cajoling, doing everything we can to persuade the States to adopt and incorporate by reference the Federal Hazardous Materials Standards, particularly for the highway activities within their State. Highway transport is just different from other forms of transport when it comes to the Federal-State relationship. Highway is so essentially local and State in nature that the only way that it is going to hang together and function properly is if the States have the equipment and the opportunities and are encouraged to monitor and to work that part of the scene.

We are encouraging States across the board for hazardous materials, not just radioactive materials, to adopt the Federal standards; apply them both intra-State and inter-State. If you happen to slop over into the rail area or the aviation area, that may lead to preemption problems, but I think that States will find enough activity in highway area to use up all available time and energies.

Secondly, within the packing and containment area, we have a notice of proposed rule making that would require type A packaging for all LSA material. I think generally type A packaging is being used today for most of it; we would seek to firm that up.

Referring back to a speaker earlier this morning and his reference to some of the rail industry's concern about shipment of casks, there are a lot of economic overtones in the position that has been taken by the rail industry. What they really want is dedicated train service, and if you push the rail people to the wall, they will acknowledge that the casks are good and that is not really their problem. They do not want the casks in trains with propane and chlorine and anhydrous ammonia and all those other bad creatures. If you look closely at what we said in the IRG report on this point, I think you will see that we tried to nudge both the shipper interests, whether they are the Department of Energy's promotional activities or the utilities, a little closer together with the rail people; get out of the ICC arguing about rates and filings and formal pleading and see what you can work out. I suspect that there has been a tendency on the part of the railroads to run the price tag up so high for dedicated trains that carry nothing but nuclear casks, that it did appear to be an outrageous cost to the utilities and the Department of Energy.

The one area of cask credibility the railroads have focussed on is the fourth of the performance criteria, the one dealing with flame testing. The test is now 1400° for a half hour. The Federal Rail Administration, our Department, working with the Department of Energy, has embarked on a series of model testing, eventually full-scale testing, flame testing at much more stringent levels than the performance standards now require. This is something that will be going on over the next couple of years. Frankly, I do not think it is going to show an awful lot more than we know now, but it should raise the level of confidence to the Doubting Thomases.

In the second area, training of persons involved in the shipment and the transportation of radioactive materials, I must say that I am very conscious when I use the term "radioactive materials," that I am talking about everything from pharmaceuticals to nuclear waste. I like to keep reminding audiences that I am talking to that we are concerned with the full range and what happens to a radiopharmaceutical has a publicly percepted impact over on the nuclear waste area and vice versa. There are distinctions to be maintained, of course, but I feel we in the regulatory business must recognize that to the general public, radioactive material means a mixed lot of things, and indeed it is.

The training of people who prepare and handle the transportation, we have regarded as basically an industry task. In this area we have, and we will continue to provide training aid material to encourage industry units that are involved in the preparation of hazardous materials, radioactive materials in particular, for shipment to provide current training to their persons who are involved in this work. Within the regulatory framework, we do now, and I expect that we will increase the places in our regulations over regulated entities; carriers, in particular and shippers to some extent. You will see more specific training program requirements in them. For example, we have, in recent years, seen a growth of specialized air carriers engaging in the carrying of radioactive pharmaceuticals. As that has occurred, the requirements that we have imposed upon them have included such things as treating their employees as radiation workers, rather than as routine airline employees. We have also included in their requirements for training. We are doing this, not just in the radioactive materials area, but we are doing it in other areas involving some of the liquified flamable gases. But still, the business of training personnel in the handling is an industry task. We are leaning on industry to perform there, and hopefully you are also.

In the third area, one that I gave the flunk mark to, monitoring, there is an extremely limited Federal capability to perform monitoring, whether you are looking at my agency, or you are looking at the Bureau of Motor Carrier Safety on the highway, whether you are looking at the Federal Avaiation Administration in the airports, or the Federal Rail Administration, in terms of casks on rail cars. The most dominant area of activity, of course, is highway. Both the Bureau of Motor Carrier Safety and my own organization are looking more and more to the State relationship in all hazardous material highway monitoring. Radioactive materials is no exception, it is just that there is a different mix of people that we work with in the States. In cases of the other types of hazardous materials, the biggest area of problem has been the bulk transport of hazardous materials in tank cars, in tank trucks, more so than the packaged materials. We work with public utility commissions, with State highway patrols, in connection with monitoring to see that there is compliance. When we get into the radioactive materials area, that is when we see a mix of people in the State. We see you along with the police activities of the State.

We have been running with the Nuclear Regulatory Commission, a loose change at the end of the Fiscal Year kind of operation, with a number of States, in performing surveillance. I think that the five or so States that are receiving a pittance from us are represented here today. Hopefully, by the end of this year, we will have ten of them on board. In the 1980 budget for my organization, if it manages to survive Mr. Duncan in the House and Senator Bayh's committee in the Senate, we may be able to put more money in at the beginning of the year, and perhaps go beyond ten States instead of waiting til the end of the year, to see what loose change we have. Bob Ryan and I have been scheming in all sorts of ways to pump more life into this particular program, to expand it beyond the straight surveillance that it has provided us over the years by encouraging the States to put some teeth into it; not only look at the stuff out there, but give the guys that are looking at it some clout to do something about it when it is not right. The whole business of State inspectors being on the scene and detecting something, and then having to come back to us through some sort of series of phone calls to find some Fed that will pay attention to them, is a slow way to do business. So if there is some way that we can devise through this process, quid pro quo with some Federal dollars, in terms of some State enforcement along with the surveillance, we are looking for it. How we get there, I am not sure, but we are looking for it.

One of the things that we have been able to do to stimulate this a little bit is some encouragement in the IRG report back to my own agency to formalize this Federal funding of State surveillance, to the point of having us look at it and propose legislation, if necessary. I think there is added recognition of the need for this in some of the pieces of legislation that are on the Hill, including some of the ones that were talked about this morning. S. 535, for example, seems to have bipartisan sponsorship; I am not sure that it correctly, or fully addresses the State relationship, because it talks in terms of planning, but it does recognize that there needs to be some financial support for States performing these tasks. Perhaps it will grow beyond planning and go into operational activities.

There are some States that are using a bit imagination today, and are using highway trust funds for purposes of helping in the training area. I know that the State of Illinois has made some steps in this direction. If you need a guide as to how to do that, what we are really talking about is highway safety program moneys, most of which probably go to procuring of driver education cars, promoting blood alcohol statutes, driver helmet laws, and the like. There are ways that State governors can channel their allocation of moneys under Section 104 of the Federal Highway Safety Act into preparedness for highway disasters; highway incidents. These include radioactive materials, as well as other hazardous materials. More and more we are seeing States channel some of those funds in that direction.

The fourth area, emergency response; here again, States have the primary role in responding to hazaardous materials transportation emergency, and their ability certainly depends upon community planning, personnel training, and the availability of equipment. Again, this is an area where the limited resources of my organization are being channeled into the development of training materials. I have left here today with the Executive Committee for consideration and feedback to us some efforts that we have undertaken in the development of a basic 8-hour training course in emergency response to radioactive materials incidents. This is being developed as an add-on to a basic 20-hour course that we have had on the street for about a year. It has been delivered to about 25,000 students. It covers the full range of hazardous materials accidents. I have also left the basic description of a textual guide to be used with the course, or it can stand independently. We are aiming to market these materials in July or August, again, depending on how much printing money I have left at the end of the Fiscal Year.

Our efforts in this area are to provide materials that have the backing and the endorsement of persons like yourselves, fire service people and others involved in emergency response, so that they will be authoritative texts that can be used by all who are in the business of training people and preparing to deal with emergency response. For many years, I believe, that we at the Federal level in hazardous materials, have concentrated too long on just the thought of containment; if you design the thing properly, the problem is going to stay in the bottle. In recent years, whether we like it or not, we have been forced to spend more and more time acknowledging that it does not always stay in the bottle, and doing something about reacting to it when it gets out and helping people to be prepared for it. These materials that we are talking about, whether it is radioactive materials or other hazardous materials, are an accepted part of our society; some are more accepted than others, but they are certainly a part of the society, and we are dependent upon them. Consequently, we must help, to the extent that we can, people to live with them and the problems that are associated, however infrequent they are.

Again, in this area of emergency response, we have seen some of the States channel their highway safety funds. I am thinking in particular of the State of Maryland that I know has recently purchased emergency response equipment. I think that they are in the process of adding to their fleet of emergency response vehicles. They are prepared to deal with hazardous materials incidents, hazardous materials spills, including radioactive material spills. Here again, this whole business of emergency response, emergency planning, has been recognized by the Congress and by various parts of the IRG report.

In the fifth area, one of my D- areas, that of review and analysis, we have incident report statistics. They have tended to indicate a good record, and I think correctly so. Last year, the 80 reported incidents, again no deaths or injuries; I am not sure this tells us the whole picture on radiation, but in terms of the classic hazardous material data collection, it says no deaths and no injuries. We do know that we are not getting all the reports of incidents that have occurred. We also know that we lack a good picture of commodity flow. We make gross estimates as to the numbers of packages and the amounts and the total number of shipments each year, but when persons like yourselves, others interested in what is happening in my community, one answers as to what is flowing through their community, we at the Federal level do not have the answers. Again, this is an item that was picked up by the IRG that has called upon my agency to develop a data bank on both shipments and accidents; that is, marrying together what we are collecting now on accidents and incidents and measuring the base against which that is reflected.

There are a number of Federal activities going on. Sandia, where the Department of Energy is scurrying madly in this commodity flow area; our own Transportation Systems Center at Cambridge, Mass. is working the problem for us in terms of ways of getting a better overall flow picture. We have had a lot of success recently at getting those kinds of pictures of rail transport of all kinds of materials, particularly hazardous materials. It has not kept the L and N on the track, but it has helped us predict where it is going to go off the next time. I think that the experience that we have gained in this commodity flow analysis will be helpful to us in the radioactive materials area, now only in terms of feedback into our own programs, but hopefully in terms of delivering something useable to the States as to what is moving and what the projections are for future movements, with a degree of particularity that you can relate to your geographic area; not gross national numbers and national pictures.

In the past, we have used the modest State surveillance program and input from that to tell us what we know about what is causing incidents. We expect to get more from that and marry that into the improved data base and hopefully more feedback to you as to what is going on in your areas and adjacent areas.

All in all, what this sums up to, is looking for a strengthening of the State role in these areas. Dealing with States, from our perspective, is preferable to dealing with individual cities. Monitoring is something that cannot be handled adequately from the Federal level, simply because the cost/benefit approach to the subject does not supplant more Federal inspectors, and perhaps it does not deserve them when you look at in that perspective. So consequently, a Federal-State relationship that is strengthened in the monitoring and enforcement area has payoff. Obviously, in the emergency response area, when something does go wrong, it is the people in the local area that are there first, that have to deal with the problem. To the extent that Federal effort can enhance and help, through training, standardizing approaches, and providing communication links and access to expertise through communications there is payoff in strengthening the Federal-State relationship.

I think perhaps the silent part of such a relationship, particularly in radioactive materials, is the increased level of confidence that governors and local governments can have through an enhanced capability within State governments to know what is happening, to know how it relates to things that are going on in adjacent jurisdictions, and what is likely to be coming in the future. Just knowing when the other "gotcha" is going to occur has a certain quietening effect that I think is beneficial to overall national concerns in these areas, and certainly to State governors and the local political officials. We all have a responsibility back to the electorate to know what is going on, to be able to answer questions, and to deal with the issues. So the idea of enhanced confidence at the State and local level as being a byproduct of improved Federal-State relationship is certainly not an item to be discounted.

DISCUSSION

MR. TEDFORD: Were all those accidents you alluded to nuclear or radioisotope-type accidents?

MR. SANTMAN: This is the total incidents reported. In the radioactive materials area an incident may mean an actual release of material or merely a suspected release of material, unlike the other hazardous materials areas. If there is a problem with a propane truck, we do not get a report unless there is a rupture in the truck. In fact, one of the problems we have had in the LNG area is that things are built so well that we have had one truck roll all the way over but never lose any products so we never hear about the accidents. In radioactive materials, we get reports on even suspected incidents. So the 80 I am talking about does not mean that there were 80 releases of material.

MR. TEDFORD: How many accidents were here; nuclear type?

MR. SANTMAN: I am not sure what you mean by an accident.

MR. TEDFORD: In the State of Georgia in the past year we have had two, which is our share. We had one on a low-level shipping cask overturned and we had one where some monazite low-level throium was dumped in a rail year in Atlanta, a low-level type of incident. Of that type of incident, what sort of magnitude are we talking about?

MR. SANTMAN: We are talking about 20 or 30.

MR. TEDFORD: That is pretty interesting, because if you look at the Agreement State program data as presented, there are about 70 or 80 incidents reported in the past year or 18 months, and there are only one or two transportation accidents categorized as such, unless they are categorized differently.

MR. SANTMAN: This is part of what I am talking about concerning our data base. It is not good enough for us to deal with. The incident reporting system that we are working with was designed to look at containment. It was designed 2 years ago to answer the question of whether or not the package was adequately designed. Packaging was the foremost thought. We need to get more things out of the information in such a way that we do not place a cumbersome burden on the reporting people to generate a lot of paper we cannot manage.

MR. TEDFORD: I concur with you that the States have a problem and a depth of interest in the transport of radionuclides within their State. It appears to me, however, that the Federal Government also has an interest in this because the majority of the roadways that go through the State that are used for transportation are Federal interstate highways. Coming back to the case of New York, did not a case in New York City actually stick? Do you have any Federal highways in New York City and what is the implication of this for other States? Is the ban effective in New York City?

MR. SANTMAN: As far as we are concerned it is. Because there is a vacuum, we have authority under a statute to get into the question of routing. The basis of the agreement that we issued, under Dr. Solon's ordinance said that although that authority existed it had never been exercised by the Federal Government. There has been, and I think rightfully so, a reluctance on the part of the Federal Government to get into street-by-street, route-by-route regulation of highway transport. Highway transport is a completely different creature in this area than aviation, water and, to a certain extent, rail. There is a tremendous reluctance on the part of the Federal Government to start telling States or localities how to regulate traffic on a particular highway. Even though it is a 90-percent Federally funded highway, the people who are out there monitoring the traffic, the people who are issuing the driver's licenses, the people who have to go out and clean up the messes when they occur are not Federal employees. There is a desire to institute of degree of uniformity to keep traffic moving in a very standardized fashion across the country yet it is not something we jump into.

MR. TEDFORD: We were interested also because a resolution has been introduced at the Atlanta City Council and was deferred when the transportation bill came. This has been accepted but there are Federal highways that go around Atlanta.

MR. NEILL: There are probably several hundred ordinances, regulations, and laws governing the transport of radioactive materials. The trend seems to be that as more and more municipalities pass their local ordinances (we will probably get up to several thousand; maybe an exponential plot), is it a policy of DOT to basically watch this or have any estimates been made of the cost to the American public as the number of regulations continues to proliferate or are you optimistic that what happened in New Mexico where a law was just passed last month where the State would preempt transportation regulations through all the counties and municipalities? What is DOT's policy in this and what is your prediction on the future?

MR. SANTMAN: This is one of the things we are wrestling with in the rule making. My own feelings on it need to be worked a bit through a few more people. I hope that I gave some indication today that I feel that part of the solution lies in a strengthening of the States' ability, particularly in the highway area. States build the highways, States maintain the highways, States generally know where the good ones are, where the bad ones are. So I think the best I can predict is that you will see us trying to build on a strengthened State relationship.

DR. SOLON: The question that I have is with respect to S-535, in terms of the special situations, environmental characteristics, population parameters, and so forth for particular local jurisdictions. I did not detect in the reading of it any kind of special respect or surveillance of the special problems that will be confronted by either States or local jurisdictions and I was wondering whether this omission in S-535 was deliberate or is it something we can still negotiate and talk about.

MR. SANTMAN: I am not quite sure. That bill, I believe, was developed by people on Senator Schmidt's staff. I know they contacted us several times, and some of the things that we said to them were reflected in changes in their early draft. There are a few things they changed but I do not know. I think that they have got some growing to do in that. I know, for example, in one area they talk about emergency planning for radioactive materials and then they jump over into nuclear waste and other areas. I think it has some basic concepts that are good, but it needs some work and I think the people who did the drafting are amenable to it.

DR. SOLON: I would just like to offer the comment to my colleagues and the Conference, that if they have not read S-535, they should take a very detailed look and offer Senator Schmidt your observations and comments along with, of course, a copy to Mr. Santman.

STATE SURVEILLANCE of RADIOACTIVE MATERIAL in TRANSPORT - GEORGIA

Andrejs Simanis
Chief, Radioactive Materials Control Section
Radiological Health Unit
Georgia Department of Human Resources

There is a widely told joke among individuals who travel quite frequently by air in the Southeastern United States which states, "If you die anywhere in the South and regardless of whether you are destined for heaven or hell you will have to transfer in Atlanta." I am sure you air travelers who have spent endless hours waiting for flight connections in the Atlanta Airport will agree with that statement.

The basic thing that joke points out is that Atlanta and Georgia are the transportation centers of the Southeast and as such a considerable quantity of radioactive material is transported within and through the State by air, highway, and rail. In a recently completed study by Dr. Bernd Kahn of the Georgia Institute of Technology, it was determined that over 15,000 shipments of radiopharmaceuticals pass through the Atlanta Airport each year with about 25 percent of these shipments delivered to users in the State of Georgia.

The fact that we are located next to the great State of South Carolina, which has one of the few operational commercial radioactive waste burial facilities and a proposed interim spent fuel storage facility, also places us in a unique geographic position. All radioactive waste generated at nuclear power reactors to the west and south of Georgia must pass through Georgia for burial in South Carolina. If the interim spent fuel storage facility is approved, then a large number of spent fuel elements will also be transported through Georgia for storage in South Carolina.

From June 1977 through June 1978, 471 shipments of nuclear fuel cycle material in the form of radioactive waste, contaminated clothing, spent fuel elements and UF_6 were transported by truck through Georgia. Of the 471 shipments, 380 were radioactive waste for burial in South Carolina, 75 were contaminated clothing for a nuclear laundry in Georgia, 12 were spent fuel elements for the Savannah River Facility in Aiken, South Carolina, and 4 were UF_6 shipments destined to the Port of Savannah for shipment to foreign countries. It was also determined that several rail shipments of low specific activity material such as monazite were transported through the State primarily to Chattanooga, Tennessee.

In early 1977, the Governor of Georgia established an "Interagency Task Force on the Transportation of Nuclear Materials." An outgrowth of this task force was the recommendation that the Governor introduce for study purposes State legislation that would seek to strengthen the State's ability to monitor the movement of nuclear materials and to respond more quickly and effectively in the unlikely event of an accident involving nuclear materials.

In the 1979 legislative session, the "Transportation of Hazardous Materials Act" was enacted to designate a responsible State agency to provide for the regulation of shippers and carriers of hazardous materials (which includes radioactive material) on the public roads of Georgia; also to provide for notification prior to entry into Georgia; to provide for rules and regulations governing such transport; to provide for permits; to provide for the authority to stop and inspect vehicles; and to provide recovery from responsible persons in case of discharge or threatened discharge of such material. The Georgia Department of Transportation was designated as the agency to implement the provisions of this act.

As you can see there is and has been considerable concern about the transport of radioactive material through the State. Thus in 1977, the Radiological Health Unit established informal agreements with several shippers of radioactive material whereby we would receive prior notification of shipments. On occasion we intercepted shipments (primarily spent fuel elements) to review labeling, placarding, emergency procedures, and shipping papers. We always informed the carrier that the material he was transporting was governed by the U.S. Department of Transportation regulations and we were conducting an informational review of his operations. With the exception of one placarding violation, which ultimately led to a $5,000 fine of the shipper by U.S. Department of Transportation, all shipments appeared to meet applicable regulations.

Next I would like to discuss a transportation incident we had in Dade County, Georgia, in August 1978. We like to refer to the incident as "the day we almost lost Chattanooga" since the incident was about 3/4 of a mile inside the Georgia border and only a few miles from Chattanooga. In fact, we attempted to give the incident to Bill Graham of the Tennessee Radiation Control Agency, but he graciously refused. A shipment of low specific activity radioactive waste, originating from the Commonwealth Edison Company, Dresden, Illinois, and bound for Chem-Nuclear in Barnwell, South Carolina, overturned at the intersection of Interstate Highways 59 and 24. The waste was contained in 18- 55-gallon drums, which, in turn, were contained within a cask that was attached to the trailer. The entire shipment consisted of 4.4 curies of radioactive material with the major isotopes being cobalt-60 and cesium-137. The shipping papers indicated that 12 of the 18 drums within the cask had surface radiation levels in the range from 1 to 2 rems/hr, and at 3 feet, 100 to 200 millirems/hr. There was no apparent damage to the cask or the trailer and the measured radiation levels of 90 millirem/hr on the external surface of the cask agreed with the shipping papers. No one was injured.

The main thing to point out in this incident is that it created a tremendous amount of interest among the media and the general public even though the barrels and cask were not breached; there was no contamination, and the radiation levels were the same as indicated on the shipping papers and these radiation levels were well within the limits for a sole use vehicle.

It appears that we as representatives of radiation control agencies have a tremendous job ahead in educating and informing the general public and the media of the hazards of such incidents so they are better able to keep the incident in its proper perspective.

GAO REPORT on the TRANSPORTATION of RADIOACTIVE MATERIALS

Michael Gryszkowiec
Assistant Director, Energy and Minerals Division
U.S. General Accounting Office

I appreciate the opportunity to speak today on our recent Report, "Federal Actions are Needed to Improve Safety and Security of Nuclear Materials Transportation." Our report addresses current Federal policies and practices and recommends several changes that we believe would improve safety and strengthen the security of nuclear shipments.

Despite a good safety record, the safety and security of radioactive materials being transported are matters of increasing public concern. In our view, the recent Three Mile Island accident confirms that accidents considered highly unlikely may indeed occur; therefore, both regulators and the regulated must not allow themselves to be lulled into complacency by good safety statistics. We believe that stronger Federal policies and regulations are needed to insure that the good nuclear transportation safety record is maintained. This is especially important in light of the projected increase in the number of nuclear shipments to be made in the near future. For example, over 2 million packages of radioactive materials are shipped annually by air, rail, and truck. The Nuclear Regulatory Commission (NRC) expects the number of radioactive shipments to more than double by 1985 to about 5.5 million annually, and spent nuclear fuel shipments, to increase more than sevenfold to about 2,200 by 1985.

I would now like to discuss the report we just issued, which identifies improvements we believe are needed in Federal regulation and which also discusses the States' role in nuclear materials transportation and Federal-State cooperation. Our report addresses several issues: (1) transportation safety, (2) security requirements, and (3) emergency planning.

INSURING TRANSPORTATION SAFETY

Three Federal agencies--The Department of Transportation (DOT), NRC, and the Department of Energy (DOE) have major responsibilities for assuring that nuclear material shipments are safe and secure. DOT regulates both shippers and carriers engaged in interstate commerce; NRC regulates commercial radioactive materials users; and DOE is responsible for regulating all of its contractors.

DOT, NRC, and DOE view safe shipping containers as the first line of defense in protecting the public from the hazards of radioactive material in transit. Packages for radioactive materials range from fiberboard boxes to 100-ton steel spent fuel casks. Our study found that while DOT, NRC, and DOE impose various package design standards depending on the type and size of shipment, they do not insure that packages are actually built to these standards. Instead, these agencies have relied primarily on container manufacturers' and users' quality assurance programs. DOE and NRC do not independently inspect packages to assure they are constructed properly, or once constructed, continue to meet Federal standards after repeated use.

While DOT recently started inspecting package manufacturers, its inspection program has barely gotten off the ground. DOT inspectors periodically, on a random basis, select individual packages for physical testing. However, this effort does not include all types of packages used for transporting radioactive materials. nor does it assure that packages continue to meet Federal safety standards after repeated use. As a result, while secure packaging is considered the primary safeguard in protecting the public, our report found that the integrity of these packages cannot be assured.

Loose radioactive material on the surface of packages and transport vehicles, referred to as contamination, is regulated by NRC and DOT. However, our study found that these agencies allow unnecessarily high levels of radioactive contamination. These levels are higher than what most nuclear industries themselves allow. As a result, transportation workers and the public may be exposed to higher levels of radiation than need be. Also, since NRC and DOT regulations require vehicles to be cleaned only to certain levels, contamination can spread to materials subsequently shipped in these vehicles.

Industry representatives we talked to criticized the DOT and NRC package contamination levels as being too high. These officials believe that it is unreasonable for NRC and DOT to allow such levels of contamination in uncontrolled areas, such as warehouses and loading docks, when these same levels would require protective measures at nuclear plants. In fact, packages contaminated to such levels would not be allowed in an unrestricted area at a nuclear facility. Even some NRC inspectors agree with the industries' position that levels are too high.

Federal regulations also spell out requirements for shipping and receiving radioactive materials. Although NRC and DOT have compliance inspection programs, neither is adequate to assure compliance with their transportation regulations. The primary reason for this is there are many shippers and receivers but few inspectors. For example, one NRC region has 10 inspectors for about 3,800 nuclear material licensees. Depending on the material handled, a licensee may be inspected anywhere from twice a year to once every 10 years. To cite another example, a DOT Federal Highway Administration region has only 25 inspectors for 1,500 shippers and 23,000 carriers. As a result, the NRC and DOT rely mainly on the integrity of shippers and carriers to comply with regulations. We believe that independent assurance of compliance is necessary to assure the public is adequately protected.

A recent DOT and NRC study using State inspectors to determine actual package handling practices and radiation exposure conditions showed noncompliance with Federal regulations. The study not only confirmed the need for better surveillance, but also illustrated the practicality of using State inspectors to enforce Federal regulations. Expanded use of existing State resources may be the best option for DOT and NRC to strengthen their enforcement of transportation safety regulations. Using State resources, on a cost-sharing basis, would be less expensive than massive increases in Federal inspection staffs. We see other advantages as well. Such a program would help State officials stay abreast of radioactive shipments, thus improving emergency response capabilities, and could help improve Federal-State relations. Also, State officials can stop vehicles on the road for inspections whereas Federal inspectors cannot.

Our report recommends that:

- --DOE and NRC, perform periodic, independent physical inspection and testing of nuclear material packages on a random basis during fabrication and after repeated use. Such inspection and testing should either be done by independent contractors or by the agencies themselves.

- --NRC and DOT reduce the permissible contamination levels for packages and vehicles to levels that are compatible with what industry can reasonably achieve. The agencies should allow the use of a higher value only when cask design or other valid considerations make further decontamination impractical or impossible.

- --DOT and NRC expand their use of existing State resources to insure that shippers and carriers comply with radioactive materials transportation regulations.

SPECIAL NUCLEAR MATERIAL AND SPENT FUEL SECURITY REQUIREMENTS

Plutonium and highly enriched uranium are routinely shipped throughout the country. In sufficient quantities, these materials can be used to make nuclear weapons. Further, only a few ounces of plutonium placed in a dispersal device can cause widespread radioactive contamination. The design and manufacture of a crude nuclear bomb is technically feasible. A plutonium dispersal device is much simpler to make. Effective security measures are necessary to ensure that these materials are not diverted for use in nuclear threats or violence. NRC and DOT have established safeguards for certain weapons-grade uranium and plutonium shipments to reduce the risk of diversion. Safeguards are used when the amounts being shipped reach a specified quantity called the strategic quantity. No security protection is currently required for quantities below this level.

During fiscal year 1977, numerous highly enriched uranium shipments, some approaching the strategic quantity level, went unguarded. On several occasions, two or more shipments were made on the same day. The theft of multiple shipments below the strategic level could provide enough material to make a bomb. There were also many unprotected shipments of plutonium below the strategic level. Plutonium of less than strategic quantities could be dispersed into the air to seriously endanger public health and safety in populated areas. We believe that these shipments may present an easy target for diversion by terrorists.

Current NRC regulations also do not prohibit consolidating two or more shipments of less than strategic quantities at carriers' terminals. Thus, two or more shipments which together exceed the strategic quantity level may be at one terminal at the same time--unprotected. Conceivably, by capturing just a few individual highly enriched shipments, or just one or two unguarded consolidated shipments, terrorists could obtain enough material to make a bomb.

Current safeguards critieria also do not adequately consider the effect enrichment levels have on the quantity of material needed to make a bomb. As a result, our study found that shipments that are less useful for making a bomb are protected, while more useful shipments are not.

Both NRC and DOE are proposing changes to current regulations that would require physical security for less than strategic quantities of these nuclear materials. But, their efforts have not been coordinated and as a result, they are proposing different levels of security. Further, both proposals do not adequately consider either the dispersal hazard associated with plutonium or the effect higher enrichment levels have on the amount of material needed to make a bomb.

The largest single source of radioactivity shipped is spent fuel from light-water reactors. Presently, the number of such shipments is relatively small but is projected to increase significantly by the mid-1980s. Because of its high radioactivity, spent fuel is shipped in massive durable casks. These casks must meet stringent Government safety rules to prevent radioactive release should a transportation accident occur. However, most shipments move without any security measures over public thoroughfares.

Spent fuel could cause a large number of casualties if widely dispersed in a successful sabotage attempt. Mechanical entry into a cask is probably not a feasible means of accomplishing dispersal. Explosive entry is more likely. Commercial shipments are not safeguarded, and we believe are accessible to such an attack.

The effects of an explosive attack on a spent fuel cask cannot be accurately predicted because no tests have been done to determine the amount of spent fuel which would actually be released if high explosives were used. We believe tests of spent fuel cask vulnerability to high explosives are needed to determine what, if any, safeguards are required.

Our report recommends that NRC and DOE:

- Jointly develop a graduated scale of security measures for the transportation of special nuclear materials, taking into account plutonium dispersal hazards and uranium enrichment levels.
- Preclude enroute consolidations of special nuclear material shipments.
- Determine if there is a need and if warranted develop a system to safeguard spent fuel from sabotage.

EMERGENCY PLANNING FOR TRANSPORTATION- RELATED ACCIDENTS

Major transportation accidents involving radioactive material require a fast, effective, and coordinated emergency response to protect the public from radiation exposure. Emergency planning and preparedness should provide adequate assurance that the public will be protected from the effects of such accidents. Our report highlights that the public currently has little assurance that they will be adequately protected in case of a nuclear transportation accident.

State and local agencies have the initial responsibility for responding to nuclear transportation accidents. Yet, many of these agencies are not prepared to effectively cope with major accidents involving radioactive material. In fact, States are generally unaware of the number and types of nuclear shipments moving through their jurisdictions.

Our study found that emergency preparedness for responding to transportation accidents needs improvement. We found that many States did not have adequate plans or did not test them.

Although the Federal Government cannot compel States to develop emergency plans, NRC and DOT now provide guidelines to assist State and local agencies in preparing their plans. The Federal Emergency Management Agency (FEMA) was established on April 1, 1979, to bring together several Federal agencies having peacetime and wartime emergency planning responsibilities. This new agency is to serve as a focal point for all Federal-level emergency planning. Therefore, we believe it could more effectively encourage State and local governments to develop and maintain emergency response plans.

Our report recommends that FEMA assume the responsibility for making policy and coordinating radiological emergency response planning for nuclear transportation accidents. The Agency should work with State and local agencies to develop and test plans for responding to accidents involving the transportation of nuclear materials and expedite the development of Federal guidelines for State and local planning for nuclear transportation accidents.

STATES' ROLE IN NUCLEAR MATERIAL TRANSPORTATION AND NEED FOR FEDERAL-STATE COOPERATION

Growing concern among the States, municipalities, and the general public about the safety of transporting radioactive material has induced many States and municipalities to pass laws and regulations to control the movement of radioactive materials through their jurisdictions. Many of these laws and regulations are more stringent and restrictive than those of the Federal Government.

Over 20 percent of the States have passed such legislation or regulations. In 1977 alone, 24 bills to regulate the transportation of nuclear materials were introduced in 19 States. Nine of these bills eventually became law. These regulations, coupled with regulations at the Federal level, impose a maze of restrictions on shippers and carriers of radioactive material. Should this trend among the States continue, the movement of radioactive material between different State and local jurisdictions could be seriously impeded, and in some cases may be virtually stopped.

The constitutional question of State authority over interstate transportation is exceedingly complex and difficult to answer. When a State and Federal law or regulation clearly conflict, State law must always yield. But, it is not so clearcut when State regulations: correspond to, or duplicate, Federal requirement; fill gaps in the Federal regulations; or enforce Federal standards as a minimum but add more stringent requirements.

A State may, as a general rule, regulate interstate shipments passing through its jurisdiction absent superseding Federal law specifically prohibiting State regulation, and there is no conflict between State and Federal law, regulations, or policy.

One of the most restrictive and controversial regulations to date is the New York City regulation essentially banning the transport of certain radioactive material through the city. On April 4, 1978, DOT ruled that the New York City regulation is not inconsistent with the Hazardous Materials Transportation Act. DOT ruled that although that Act authorizes DOT to issue a routing regulation--a regulation prescribing authorized transportation routes--DOT had not yet done so. Thus, the New York City restriction could not be deemed inconsistent with a Federal regulation, which did not exist. Reaction to this ruling indicates that States may become even more active in regulating nuclear materials transportation.

A proliferation of State and local regulations could turn routing a shipment into a major task. Lack of uniformity among regulatory entities could force carriers to take longer, more hazardous routes, and could create economic hardships for shippers. While the Hazardous Materials Transportation Act has been in effect since January 1975, DOT has not yet issued regulations governing the routing of radioactive materials shipments and does not expect to do so for at least another 2 years.

In our report we point out that DOT was unaware of all the regulations and legislation that State and local governments were passing, and was not always responsive to States' concerns about transporting radioactive materials. We believe that regulations imposed for political and emotional reasons may not result in the safest and most expeditious means of transporting radioactive material.

In our report, we recommended that DOT expedite its efforts to develop, after coordination with States, a routing regulation for radioactive materials shipments. We also recommended in a more general sense that DOT develop a program of coordination with State governments, making sure that State and local concerns are adequately addressed in developing Federal transportation regulations.

In closing, we feel more needs to be done to assure that the transportation of nuclear materials in this country is safe and secure. We believe our report highlights areas needing attention and action. We hope you find the report helpful.

DISCUSSION

DR. SOLON: One question that I have is addressed to S-535 which will be the umbrella regulation that will dictate the transportation of radioactive materials. Has the Comptroller General's Office taken a position or have they reviewed or evaluated, or are their inputs available to Senator Schmidt and the drafters of the bill?

MR. GRYSZKOWIEC: We will be commenting on the legislation but we have not formalized a position yet.

CONCURRENT SESSION C: OPTIMIZING RADIATION USE

Moderator: *Gerald W. Allen*, Kansas

NUCLEAR MEDICINE-QUALITY ASSURANCE PROGRAMS
Arthur B. McIntyre, Acting Chief, Nuclear Medicine Branch, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

AAPM'S QUALITY ASSURANCE ACTIVITIES
Robert G. Waggener, University of Texas Medical School, San Antonio, Texas

QUALITY RATING OF DIAGNOSTIC X-RAY FACILITIES
Charles M. Hardin, Manager, Radiation Control Branch, Kentucky Department for Human Resources

A STATE'S INVOLVEMENT IN QUALITY ASSURANCE
Maury Neuweg, Chief, Division of Radiological Health, Illinois Department of Public Health

QUALITY ASSURANCE IN AN UNCONTROLLED STATE: NEXT AND BENT IN IOWA
Roger W. Cochran, Hygienic Laboratory, University of Iowa

THE USE OF QA ACTIVITIES IN LIEU OF A REGULATORY HAMMER
Edd Johnson, Chief, Radiological Health Services, Division of Health and Medical Services, Wyoming

NEXT/DENT COMPARISON STUDY
Fred G. Rueter and George H. Koustenis, Analysis and Evaluation Branch, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

USE OF BENT IN OKLAHOMA
William M. Kemp, Occupational and Radiological Health Services, Oklahoma Department of Health

PATIENT EXPOSURE REDUCTION BY "LIMITS"
Dale E. Gergely, Division of Radiological Health, Illinois Department of Public Health

PATIENT EXPOSURE IN CHEST RADIOGRAPHY
Richard E. Gross, Chief, Quality Assurance Branch, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

IT'S TIME TO TALK ABOUT RED (RADIATION EXPERIENCE DATA)
William S. Properzio, Director, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

CONCURRENT SESSION D: RADIOACTIVITY CONTAMINATION PROBLEMS AND NATURAL AND ACCELERATOR PRODUCED RADIOACTIVE MATERIALS

Moderator: *Heyward G. Shealy*, South Carolina

NARM OVERVIEW
Edgar D. Bailey, Administrator, Radiation Control Branch, Texas Department of Health

NORM OVERVIEW
L. Hall Bohlinger, Nuclear Energy Division, Office of Conservation, Louisiana State Department of Natural Resources

RADIOLOGIC ASPECTS OF ZIRCON SANDS
David G. Wagstaff, Radiation Control Section, Oregon State Health Division

FIELD SURVEYS OF PHOSPHATE SLAG USE IN SODA SPRINGS, IDAHO
Bruce H. Peterson, Radiation Control Section, Idaho Department of Health and Welfare

NORM STUDIES IN THE STATE OF WASHINGTON
Ellen G. Haars, Occupational Health Section, Health Services Division, Washington Department of Social and Health Services

RADIUM REMOVAL FROM WATER
Lewis M. Cook, Chief, Environmental Surveillance, Radiation Control Branch, Division of Occupational Health, Texas Department of Health

STATUS OF CURRENT STUDIES OF RADON IN PUBLIC AND PRIVATE WATER SUPPLIES IN NEW ENGLAND
Wallace W. Hinckley, Manager, Radiological Health Program, Maine Bureau of Health

RADIOACTIVITY ASSOCIATED WITH SELECTED MINERAL EXTRACTION INDUSTRIES
Donald W. Hendricks and Vernon E. Andrews, Office of Radiation Programs/Las Vegas Facility, U.S. Environmental Protection Agency

THE ROLE OF THE BUREAU OF RADIOLOGICAL HEALTH IN NARM EVALUATION
Allan C. Tapert, Radioactive Materials Branch, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

THE CONDOS METHODOLOGY FOR EVALUATION OF RADIATION EXPOSURE FROM CONSUMER PRODUCTS
F. R. O'Donnell, Technology Assessments Section, Health and Safety Research Division, Oak Ridge National Laboratory

LICENSING FOR STATE CONTROL OF NARM
Paul D. Eastvold, Acting Manager, Radioactive Material Licensing, Division of Radiological Health, Illinois Department of Public Health

NUCLEAR MEDICINE-QUALITY ASSURANCE PROGRAMS

Arthur B. McIntyre
Acting Chief, Nuclear Medicine Branch
Division of Training and Medical Applications
Bureau of Radiological Health, FDA

Nuclear medicine has come of age. It is time for State radiation control agencies to reevaluate their position with respect to the application of radionuclides in medicine. Diagnostic nuclear medicine procedures in the United States during 1979 may number as high as 14 million. The per capita contribution of nuclear medicine to ionizing radiation exposure in the United States is in excess of 10-million rads per year. Although this is much less than the 72-million rems associated with medical x rays, it is substantial enough to warrant more attention to use control activities in this field of medical imaging.

The Bureau of Radiological Health has been promoting the implementation of quality assurance programs for nuclear medicine since 1973. The subject has been on the Conference agenda each year since the meeting in Springfield in 1976.

One immediate result of the Springfield presentations was the adoption of a resolution by the Executive Board in June 1976:

Resolution

WHEREAS, the continuous improvement of nuclear medicine scintigraphic instrumentation will yield high quality diagnostic images;

WHEREAS, such images are essential to the evaluation and clinical management of nuclear medicine patients;

WHEREAS, it should be the goal of all nuclear medicine departments to maintain a high level of diagnostic accuracy in interpreting scintigraphic images; and

WHEREAS, such accuracy can be achieved in part by insuring the standardization of the performance of scintigraphic imaging instrumentation;

BE IT RESOLVED, that scintigraphic instrumentation used to collect nuclear imaging data shall be quality control tested each day of use for minimization of variability in the following performance parameters:

a. UNIFORMITY - the ability to produce a uniform image of a uniform "flood" source;

b. SPATIAL DISTORTION - the ability to image arrays of linear sources of radioactivity with a minimum of distortion;

c. RESOLVING POWER - the ability to produce and display images of an array of radioactive sources which shall be discernable as separate entities.

Three years have passed and the number of nuclear medicine procedures performed each year has continued to increase at a rate ranging between 25 and 30 percent per year. I have a question for the Conference. In that 3-year period, what has been done by your agencies in the way of implementation of quality control programs for scintillation cameras? Is there a place for the State agencies to play an effective role in nuclear medicine quality assurance? Certainly the answer in both cases should be yes. However, for many reasons, few States have initiated active programs in this area. The following challenge is offered to the Conference: As nuclear medicine now represents more than 15 percent of the total ionizing radiation exposure from medical and dental diagnostic procedures, how can a State responsibly refrain from active participation in evaluating quality assurance practices in this field? Although an equivocal or unsatisfactory procedure in nuclear medicine does not necessarily result in a repeat procedure being performed, such procedures are misuses of radiation and contribute unnecessary radiation to the patient. False positive or false negative results because of equipment or radiopharmaceutical problems are also useless and unnecessary radiation. A procedure that must be repeated because of such problems does not always require a readministration of the radiopharmaceutical, but does take additional time in terms of equipment and professional staff. This, of course, increases the cost of nuclear medicine procedures both to the facility and to the patient. An effective quality assurance program optimizes the quality of the diagnostic image obtained while minimizing ineffective and unnecessary exposure to the patient.

The Bureau is in the process of developing voluntary recommendations for quality assurance programs in nuclear medicine facilities. The recommendations will address most types of instrumentation and the radiopharmaceuticals used in this diagnostic practice. A Notice of Intent to develop recommendations will be published in the FEDERAL REGISTER within the next 3 months. Implementation of the recommendations when finalized will be accomplished through educational efforts coordinated by the Bureau and conducted in cooperation with professional organizations and public agencies involved. Evaluation of the success of these voluntary recommendations requires that the current level of quality assurance practiced in nuclear medicine laboratories be determined. Such evaluation can be most objectively handled by individual State radiation control programs during their normal surveys of the facility's radioactive materials license. Currently, we are developing an evaluation methodology through which use control agencies, such as the State radiation control programs, can evaluate the application of quality assurance programs in nuclear medicine facilities. Active participation by the State agencies in developing and testing this program is invited.

AAPM's QUALITY ASSURANCE ACTIVITIES

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

Maybe we are approaching radiation dose production the wrong way in a lot of respects. You know, life insurance actually started in England and it did not do any good because they called it "death insurance." It was brought over to America and some Yankee salesman changed the name to "life insurance." It took off like a rocket and it has been one of the major forces in America today. Well, maybe we are reducing radiation dose the wrong way; maybe we ought to put a different fillip on it or a different twist and maybe we will bring up some of these ideas.

The American Association of Physicists in Medicine had a number of quality assurance activities involving uses of both ionizing and nonionizing radiation. I am going to talk briefly about these activities, and I am going to emphasize diagnostic radiology because while you say it is not the principal thing it is the money involved. That is where all the radiation dose is that we have impacted on.

We have activities in several areas in diagnostic radiology. We have them in nuclear medicine and radiation therapy and ultrasound. I am going to confine the majority of my remarks to diagnostic radiology because that seems to have been--where most impact is made and other, and many very good programs in quality assurance have been initiated by other organizations in other areas. The AAPM has developed a document, our Report No. 4, Basic Quality Control in Diagnostic Radiology. This is a document with a long history and had a little controversy at times along the way. This is an interesting document in a sense that it is a document aimed at the technologist's level. It is a document intended to be implemented in the field. In fact it is in field use at this time and is a document that was developed by a consensus group. It is a consensus document in the sense that approximately 50 people input to this document with a number of meetings and a number of writings over a period of time. The document is intended to present a list of procedures that would be used by a person in an institution, using very simple tools and very inexpensive tools, too. We feel that a fairly good quality assurance program can be implemented with this document.

We recognize there are many quality control procedures in diagnostic radiology and a lot of people use it. There is no known way that is considered the best way, but all we are saying is that there are a number of procedures that any prudent person would agree are reasonable with reference to quality control in diagnostic radiology. We have simply tried to put down the easiest to implement in this report. We recognize that there are many very satisfactory quality assurance procedures in practice in the United States.

In putting this document together we got the best expertise that we could and we went to many organizations outside of AAPM and many experts had it. Some of the people in this room have contributed to this document. We feel that it represents a distilled knowledge of quality assurance procedures in diagnostic radiology and we do not think that there are any glaring errors in it.

A quality assurance program is one of the rare things that if you look at it closely, everybody is a winner. Nobody is a loser with a good quality assurance program in diagnostic radiology, or in any uses of ionizing radiation. Everybody wins.

The first thing that happens is that we increase diagnostic information. Reading the uses, if you consider ionizing radiation and nonionizing radiation, getting diagnostic information from it is a lot like driving drunk. You drink a little and your physiological reflexes are impaired but you really don't know it and you don't sense it yourself--only until you are really drunk. As a diagnostic system is not optimized, the average viewer or even an expert viewer does not know the difference. A system has to change several percent before even the most expert viewer knows that something is wrong. Whereas QA procedures will pick this up. So the information content can be impaired seriously and not even the most expert viewer will know the difference.

A quality assurance program of a certainty will result in a lower patient dose. This is I think incontrovertible and I do not think anyone would argue too greatly with it. The best example is just simply eliminating retakes; it will eliminate a substantial percentage of radiation dose and obviously in reduced cost. Interestingly enough, in the best institution, a quality assurance program may not be cost effective, if they are already doing it. In other words, in the very best institution, it is a marginal thing but they will do it because of increased information and lower dose. But in the average institution, a quality assurance program will pay for itself monetarily.

We have talked about the diagnostic quality of the procedure. In fact of the matter, a proper quality assurance program is really maybe the only way to insure the diagnostic quality of the procedure. In this little innocuous aside, probably is the focal point of implementing quality assurance programs. It is getting to where people want to pay for what they alledgedly are getting. And if the only way that a third-party carrier can truthfully assure themselves that they are paying for diagnostic quality information is via some kind of program like this, this is a fulcrum point or a leverage point outside of the norm of your regulatory sphere. It is very simple and very easy.

We have talked of radiation dose and I always think about the Hans Christian Andersen story of the Emperor's Clothes. The Emperor does not have anything on. I always think of this and often wonder why do we have regulations and why we go over regulations. We are always talking about regulations but a quality assurance program is the easiest way to reduce the average population dose in America today without any question at all.

A reasonable reduction goal for the average exposure from diagnostic x-ray exams in America, would be 20 millirems per person per year. This is I believe a reasonable goal and I do not think there is anything at all unrealistic about it. There is some evidence for this. Let us just take for example the area of retakes. I do not really know what the retake percentage in America is, and nobody else does either. But I have heard numbers anywhere from 5 percent to 15 percent. In the worst-case, 15 percent; and in a very good institution, 5 percent. Let us say 10 percent is the number of retake. You eliminate half of the 10 percent; that is, 5 percent. Also we have evidence in the mammography exposure studies. I know that some of the activities in which AAPM was involved, they made measurements in mammography, and they have all been published and you are all familiar with these. Do you remember when you used to see average exposures and they ranged from one rad to 50 rads and things like this? In recent years, or in recent vintage time we see that the average numbers are dropping ....now. I know it is possible to cut this most dramatically, in fact, with an improvement in image quality.

I would make a few suggestions. In order to effectively implement a quality assurance program, it requires a minimum training of a few days, and I did not specify the number of days. It will vary with each individual's estimate, but it takes a few days training for even a highly qualified or motivated person, technologist. I feel fairly strongly that this is a correct position, that it takes a few days training for anyone in order to effectively implement a quality assurance program. The program also has to have the support and backing of an institution or it is doomed to failure. The best way to get backing of an institution is by the pocketbook. This is done most effectively outside of the normal regulatory channel that we are discussing at this Conference. I do not mean to tout (I guess I am touting this as a universal panacea for all the problems of radiation control), but I cannot think of any negative features associated with a nationwide quality assurance program.

Getting back to our 20 millirem a year reduction. You know we bandy about numbers of how much money we save, how much is a rem worth or a rad worth. If any of you are taking notes, if you will multiply 0.02 times 2 times 10^8 and then leave a parenthesis for what a rad is worth, you will see some very large dollar numbers come up as far as the dollar value of the quality assurance program in America today. I have heard values of the rad from anywhere from $100 to a $1,000 as far as future medical cost.

AAPM has been very active in radiotherapy and we have published a number of codal practices and protocols, and so forth, so if you are doing radiotherapy and you are not using our documents, you should be in trouble.

Nuclear medicine is an area that has been very active in other associations but we are developing a quality assurance protocol. Again, I want to emphasize that there are many fine protocols. A number of people have done this. I am going to close my talk with one general observation:

A quality assurance program should be a consensus program. No one agency or no one society or association should take the lead completely in this. It should be a consensus report. It should be a consensus movement of industry, government, consumer, third-party carriers, and so forth. It is in the best interest of all parties and as I said, after really searching my mind, I cannot think of any negative features associated with a broad-based quality assurance program.

DISCUSSION

MR. STOCKS: Where is that AAPM No. 4 available?

DR. WAGGENER: It is available from our headquarters in Chicago.

QUALITY RATING of DIAGNOSTIC X-RAY FACILITIES

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

I want to first indicate to you that I am not going to be talking about quality assurance. Most of the papers that are given this morning are on the subject of quality assurance. Mine is quality rating but not quality assurance. The question is, Is your x-ray program effective? And obviously I am directing this this morning to the State Program Directors.

Do you have a method to measure this effectiveness? Do you have a system to determine priorities of inspection? Maybe the first question I should ask is, is it important to have a method to evaluate your effectiveness and set priorities? If your answer to the last question was no, you can leave since the talk will be of no value to you. On the other hand, I feel sure that you are all compelled to answer the question, yes, so I will proceed.

Over the past several years, several individual States and the Conference have developed ideas and concepts to answer these questions. As an example, in 1968, we in Kentucky initiated a program, a priority system, for the inspection of x-ray facilities. This system was published in the Radiological Health Data and Reports in August of 1970. The system, in brief, was based on the assignment of debit points or negative values to items found in noncompliance during inspections. These debit points for each machine in a facility were then totaled and multiplied by the workload of the facility, given a facility number or priority number. From this system we were able to group facilities with high-priority numbers together for inspectional purposes. The system also provided data for comparison of disciplines, machine-type comparisons, and other information. In addition, by comparing the priority number from year to year, a measuring stick for effectiveness was developed. It should be noted that the system was based on compliance items only.

In 1972, the State of Kansas developed the concept known as State Effectiveness Index. This system was more directed at measuring the increase or decrease of radiation exposure based on x-ray inspection data. With this system, weight values were assigned to specific mAs per film, roentgens per film; or for fluoroscopes, roentgens per minute as determined from the inspection. These values were further effected depending on the use or nonuse of gonadal shielding, proper collimators, and proper filters. Each machine received a calculated number, based on the above and then a total of all machine values in the facility gave a facility State Effectiveness Index number. The Index could than be compared from year to year to show changes based on a representative sample of inspection. About the time that the SEI concept was being evaluated by a Conference Task Force, the NEXT Task Force was formed. At the annual meeting in New Orleans, the concept of organ dose index and skin exposure index was introduced. As we all know, this system has in fact provided a method to show trends, compare projections, and in general provide various means to evalute the effectiveness of our x-ray program.

The system is continually being evaluated for improvements and has in fact provided an excellent tool to measure certain aspects of the State x-ray program. However, the NEXT system is designed to do specific things. It provides the user with data, which, when properly evaluated, can be used to measure various parameters of the system. However, there are certain areas that would be useful in program evaluation but for which the NEXT system was not specifically designed. For example, although much of the data collected by the NEXT system provides information, which, when properly used, would show the need for quality assurance programs at a facility, the system in itself does not provide the method to use in using the data for that purpose. As you have heard me speak before and as we have already seen with the two previous speakers, quality assurance is a very important item and this is one of the areas that I am going to try to show you a little bit about in a few moments, very lightly though.

Since 1973, we in Kentucky have had to state our objectives by the objective system method, stating quantifiably what we expect to do in the next coming fiscal year. We tried several ideas over the years, each of which have had certain drawbacks. In 1977, the concept of quality factor rating was introduced. The basic concept of this facility rating system uses components of our previous priority system while taking advantage of data collected from our NEXT inspections. One of the major improvements in this system over the earlier priority system, is that it considers not only regulatory items, but some nonregulatory items, and these are quantifiable. First let me clarify the term quality as used in this system.

In this system, quality does not relate to image quality. It refers only to the quality of a diagnostic x-ray facility relative to a specific value of quality established by the program as a goal to reach. It does not relate to quality of medical care from that facility. It should however, relate to the level of a given facility in producing x rays with the least amount of unnecessary radiation exposure.

The objective is to enable the rating of diagnostic x-ray facilities quantifiably, which will include as many aspects of radiation protection as possible, both nonregulatory and regulatory. The second objective is to provide for establishing inspection and reinspection priorities in diagnostic x ray, provide a method to measure progress in meeting program goals in diagnostic x ray, and provide a method to identify facilities in which QA activities may be more effective.

The overall objective that we had for last fiscal year, was to have each diagnostic x-ray facility obtain a quality factor rating of 94 points or greater with a 100 points being perfect. The 94 points is an arbitrary number which appeared achievable. A value of 100 points may seem achievable but some facilities can still have good quality without being perfect. Therefore, we arbitrarily chose 94 percent of perfect as an acceptable goal to reach.

Before going into the details of the system, I must say that initially we tried to be very fancy and complicated. We are proposing to use a more simplified system for the next fiscal year and what I want to describe today will be this more simplified system rather than the original complex system. As stated in the objectives of the system, we want to quantifiably measure both regulatory and nonregulatory items. Therefore, we have chosen specific items from the regulations, those which we feel will most effect radiation protection, and have assigned weighted values to these items based on their overall impact on radiation protection. Additionally, we had chosen two nonregulatory items--projection exposure ranges and projection monitoring exposure ranges. We have applied them to medical radiographic, fluoroscopic, and dental radiographic.

Figure 1 shows the numbers that we have actually assigned to the various items. As an example, a greater value given to collimation which is a value of 10 compared to tube stability, which is an item of 1. Under the dotted line over on the bottom, are the two nonregulatory items, projection exposure ranges and personnel monitoring exposure ranges. We have similar numbers for the fluoroscopy unit. Again, they are arbitrary numbers that we have assigned. You may disagree with these, you may want to put more emphasis on one area versus another area. In dental, we have a very similar situation; and how did we get the numbers that go at the bottom, the nonregulatory numbers? I mentioned the suggested exposure ranges for each projection. These are the same numbers of which there was some controversy about during our evening at the Cheese and Winery the other night. Those numbers basically represent the second and third quartile of All States data from the NEXT system and if one particular individual tube for a projection falls outside of those ranges, they will not be given the points at the bottom of the other side. If they are within that range, they will.

Medical Radiographic

Item	*Weighted Value*
A. Regulatory	
1. Collimation	10
2. Beam Quality	10
3. Timer	4
4. Exposure Switch	4
5. Environmental Shielding	5
6. Operator's Protection	5
7. Personnel Monitoring	5
8. Tubehead Leakage	1
9. Unauthorized Persons	1
10. Tube Stability	1
11. Gonadal Protection	8
12. Machine Warning	1
13. Technique Chart	4
14. Regulations Available	1
15. Area Posted	1
16. Part 165 (Worker Regs.)	3
17. Operator Certification	10
18. Exposure Reproducibility	7
19. Timer (Darkroom)	3
20. Thermometer	3
21. Darkroom Light-tight	2
22. X-ray "On" Indicator	1
23. Proj. Exposure Ranges	0 or 5
24. Personnel Mont. Exposure Ranges	0 to 5
TOTAL	100

Figure 1

I would like to clarify something right now. We are using these guides to stimulate us to look closer. We do not necessarily state if a facility or a projection is outside that range, it is not necessarily nonacceptable. It may be acceptable after we evaluate it. At least it gives us a key in which to evaluate. All of you know you have gone into facilities in which the quarterly occupational exposure may be several hundred millirem, compared with another facility which has a few hundred millirem or even less than a hundred. Neither were in violation of your regulations. On the other hand, one was obviously doing a little better job than the other one, at least as it relates to the occupational exposure. So depending on whatever the level is we see there, that is the way we give the point value.

After the inspection, a form is completed, tabulating the total point value for each tube in the facility, but a tube with a poor quality rating and high workload should cause more unnecessary population exposure than a tube with poor rating and low workload. Therefore, we have tried to introduce a workload factor into the system and I might say we are having the most trouble with this right now and definitely need some improvement in refinement for the system. We are subtracting points because of high workload versus a low workload. The values will be subtracted--now this is per tube not per facility--but this is per tube. After these calculations are made, each tube inspected at the facility now has a point value and since the total possible points is based on 100, the point value can be considered as a quality factor value for each tube. For the total facility, these individual tube quality factors are than averaged providing one value, or average factor, for the total facility. With this value we now have a quantifiable method to measure the quality of the facility which has considered both regulatory and nonregulatory items.

What about the other objectives of the system? Obviously for inspection and reinspection priorities, such priorities should be based on quality factor rating; the lower the QF receiving higher priorities and inspections. As it relates to identifying facilities in which quality assurance programs would be the most effective, again a lower QF rating in general, would indicate those facilities in which QA program should be considered. But in particular, those facilities with a low QF specifically in the nonregulatory items.

And finally, how can the system be used to measure progress? We are required to measure our progress quarterly and annually. After the inspections, a registrant is cited for the noted violations, and recommendations are made that would address the nonregulatory items, such as an unusually high exposure film badge record. The facility is usually given 60 days to correct the violations, but to provide us time in preparing reports, drafting letters, mail turnaround plus some delay in violation correction by the registrant, we allow a 3-month interval to measure progress. Except for very unusual cases we accept the written response of the registrant with valid invoices enclosed as sufficient evidence of violation correction. Therefore, after the 3-month interval, from the original inspection in which a facility received an original QA rating, we will redo the form reflecting the corrections made by the registrant. With these corrections now reflected, the facility will have, should have, a higher QF rating. Therefore, we can measure our progress by showing the upgrading of QF rating on each facility inspected through our enforcement program and our recommendations that are made. Figure 2 shows the initial and corrected QF for different disciplines, the first being physicians, the second, dentists, the other is chiropractors, and the other is hospitals. The darker shaded area was the average QF for that facility initially; after we gave a 3 month's time period for correction you can see the lighter shaded area.

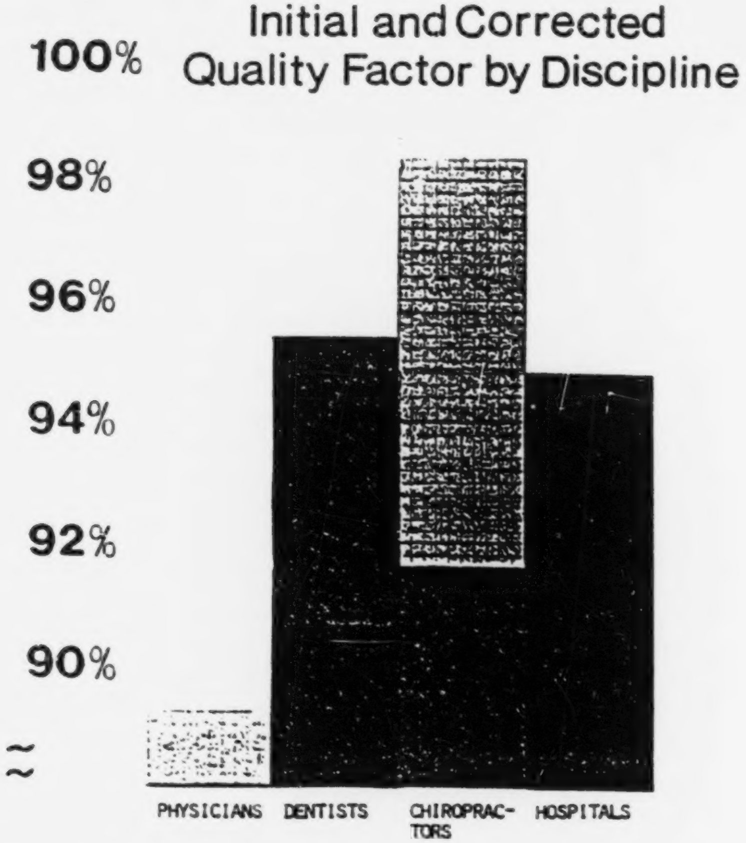

Figure 2

It can be seen that all disciplines, physicians, dentists, chiropractors, and hospitals initially fell below the desired 94 points. The extension of the bars with the lighter shaded areas show that following compliance actions, we were able to raise the hospitals, chiropractors, and dentists to the desired level of 94 or greater. We have therefore a measuring stick of effectiveness and did reach our goal for these three disciplines. An analysis of the data indicated that the primary reason why the physicians did not rise above the 94 points was because of the large number outside the exposure ranges for the projections. This would indicate the need to concentrate QA nonregulatory activities toward physicians. Some other interesting aspects of this Figure show that when initially inspected, hospitals had the highest average QF of 92.8, but through corrective actions, less change or impact was made, only a 2 percent change. Whereas with chiropractors, the change was much more dramatic, a 6.8 percent change. A further analysis showed that this small change for hospitals was influenced greatly by the high workload of these facilities compared with the low workload of the chiropractors.

Then last, in Kentucky, we have four regional offices and conduct our inspectional program from these regional offices. We know due to the manpower unavailability in the western part of the State that we should have a lower QF rating. There just has not been that much work done compared with the rest of the State. We now have that position filled. We anticipate in the next fiscal year that that quality factor should increase in the western part of the State. We have concentrated most of our effort in the metropolitan areas of Louisville and Lexington, and these areas had the highest quality factor rating. So it can also provide you, by doing it in this method, some manner of prioritizing for regionalization.

In summary, we have developed a system for rating diagnostic x-ray facilities and this rating system has provided the mechanism to quantifiably measure program effectiveness, establish priorities of inspection, and help identify QA needs. The system still has some refinements and polishing but appears to be on a workable level.

DISCUSSION

MR. BENSON: How did you get away with developing this program without any Bureau help?

MR. HARDIN: There is a fellow in the Bureau who helped start this whole thing many years ago, Mr. Dillard. In our initial priority system, he was one of the major instrumental fellows who got us started on this thing.

MR. BENSON: If you look at the overall results, as on your bar chart there, everything is clustered about the 95th almost or the 90th percentile of perfect. In other words, everything comes close to 100 percent. My perception of the art of x-ray utilization, perhaps using BENT data as an example, is that we have been able to reduce exposures by as much as one-half sometimes even more than one-half. That seems to me to be a more honest picture of the overall quality or the overall state-of-the-art. I am just wondering what you will do in a couple of years, for example, when you cannot keep pushing up against 100. I just do not think it is that good, I guess.

MR. HARDIN: I fully understand what you are saying. What we would love to be able to do is to add every year or so more and more nonregulatory items that would have quantifiable numbers and the thing that you are talking about, that we have difficulty with is evaluating some nebulous quality which we cannot quantify and thus cannot accept. The people who look at our objectives say "don't tell me how many inspections you are going to do, that is a method to get an objective. State it in some type of objective I can understand." And its got to be quantifiable. We would like to see all the various qualities be included but it has to have a number tied to it or we cannot use it.

MR. SOURKES: Regarding your assessment of facility according to workload, I would suggest that the workload be assessed according to the mAs used per procedure and totaling this up over the week. It comes out usually in milliampere minutes. You have to factor in, of course, the kVp at which the procedures are operated. But you can go far wrong just totaling up procedures where you have some units that are used only for chest shots and some units that are used for mammography and there might be as much as a factor of a 100 difference in associated dose. I think that could be reworked with a better assessment of the workload on a technique basis.

MR. HARDIN: As I indicated, I certainly do believe that we have to try to correct and improve the impact of the workload on the system. I think it is not overweighting the system somewhat and I appreciate your suggestions and we will certainly consider that.

MR. HEIDERSDORF: I think I misunderstood how you used the workload point system. As the workload increased you subtracted more and more points. You set as a level, your objective, 94 points. What do you do in the case of a high workload facility in which you are subtracting a large number of points, it is impossible for that facility even though it could be perfect in many respects to have a 94 score. I do not see how that is used.

MR. HARDIN: the facility is 100 percent in all the regulatory items and the nonregulatory items, either one, we do not apply a workload factor. So there will be nothing subtracted, they will end up with 100 points. That is very unusual for that to occur but it is possible. Now the point that you are making now is one of the things that has given us the most trouble. It does happen, however, that for most facilities that have more than one tube, it seems to average out. We have found several tubes that would meet perfect 100 whereas in the same facility another tube may rate a 75 or an 80. Thus, the final number that we are using to evaluate the facility has been brought up to 94 and above in most cases after the 3-month period of time. We do believe that after 3 months in most facilities we can bring them up close to the 100 points. The only place we cannot is in these nonregulatory items, and we are going to get them on the regulatory. It is a problem and we do need to adjust. I almost did not bring this paper to this meeting because we are still having problems with it but I wanted to get the concept out to let you see what we are trying to do. I think we will have it refined by next year to a really good tone.

MR. HEIDERSDORF: I noticed you had a very high point value assigned to gonadal shielding which I think all of us would agree to. But is this based on whether or not gonadal shields are present or would you attempt to verify in some way that they are used. There is, of course, a big difference.

MR. HARDIN: This has to do with our regulatory requirement which is to determine (1) that the shielding is there and (2) that it is used.

A STATE'S INVOLVEMENT in QUALITY ASSURANCE

Maury Neuweg
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Illinois Department of Public Health

The words "Quality Assurance" seems to be the new "buzz" words in the field of diagnostic radiology today. There are several organizations, both public and private, discussing the virtues of a QA Program for radiology departments. X-ray film companies, professional societies, Federal agencies, and certain State agencies have been, or are currently, involved in "spreading the word" about quality assurance--relating what it means, how it works, what it will do for the x-ray department and, most important, what it will do for the patient undergoing a radiographic examination. We in Illinois have only recently, jumped on the band wagon, by becoming actively involved in this rather new program.

Our interest in initiating action in our State toward quality assurance was brought about as a result of my participation with the Quality Assurance Task Force over the past couple of years. As most of you are aware, our Task Force developed a draft document that was distributed at last year's meeting in the now world-reknown city of Harrisburg! That draft document has undergone another revision, mainly because of some very good comments received from several States, as requested during the regional meetings last fall. I wish to take this opportunity to express my thanks on behalf of the Task Force for your comments and cooperation to improve the document. We plan to print and distribute the final document once we have the concurrence of the Executive Board.

As you may recall, the Quality Assurance Manual--which, by the way, will be referred to as a Guide for State Program Implementation--indicates three different levels of State participation. These levels of participation were discussed in Chuck Hardin's paper at last year's meeting. To refresh your memory, the first participation level is that of a mailout system by the State to selected medical x-ray facilities. This consists of mailing promotional materials such as pamphlets or brochures and a cover letter to facilities describing the parameters involved to reduce patient exposure, improve image quality of the film, reduce retake rates, and decrease facility operational costs.

The second level is that a designated individual within the State program could be trained to become the "QA Promoter." This individual would become familiar with QA techniques and could visit selected facilities, using promotional techniques, such as a flip chart, to attempt to "sell" the need of implementing QA within that facility.

The third level of participation specifies that either one individual--or possibly all medical x-ray inspectors within the State program--become trained in QA parameters so they can visit medical x-ray facilities and actually perform measurements on the automatic film processors and the x-ray machines. This is a type of "show and tell" method attempting to convince key people within the x-ray department of the benefits associated with QA. Those key people are the chief technologist, the chief radiologist, and the facility administrator. All three of these key people are important to the implementation and continuation of quality assurance within the x-ray department.

We have decided to attempt a combination of the second and third levels of participation. One of our experienced x-ray inspectors has been trained by the Bureau of Radiological Health in Rockville and has been provided with proper equipment to perform measurements on the processor and the x-ray machine. This has occurred since Illinois has been selected as a "Pilot State" by the Bureau, to test the different levels of State participation and determine what works and, more important, what does not work. We actively began our involvement in QA in January of 1979. The trained inspector on our staff is located in our

Chicago office and has been working full time on this project since January. For our initial phase, we decided to limit our efforts to hospitals only. There are 100 hospitals in Chicago and the surrounding suburbs. Of these 100 hospitals, 40 were contacted and asked if they were involved at all with quality assurance. Of those 40 contacted, 14 indicated they did have an active quality assurance program of some degree. Twenty-six hospitals indicated they were not involved in any type of quality assurance. Therefore, it is anticipated from this sample that approximately 35 percent of the hospitals are involved at least minimally with quality assurance.

During these initial contacts, we were only attempting to collect general information concerning the good and bad points they have determined as a result of their quality assurance efforts. I was hoping to have some concrete data to present at this meeting; however, because of the limited time we have devoted to our QA efforts--roughly 3-1/2 months--I can only share with you some of the general attitudes and results of our study thus far.

First of all, we are pursuing our QA efforts on a nonregulatory approach. We are stressing, during each facility visit, that we are collecting information to make us more aware of what the real situation is regarding QA and we want to share the benefits with others. We have found that a majority of the facilities feel somewhat apprehensive in revealing pertinent information regarding their QA activities, since they feel we will use this information to develop regulations to be used against them in the future. It is therefore difficult to demonstrate the service approach by a State inspector.

Second, approximately 90 percent of the facilities involved in QA were only monitoring the automatic processor on a somewhat varied frequency. No one had established a routine schedule of either monitoring or measuring the various parameters on the x-ray machine to maintain reproducibility and consistency of exposure output. It appears the main emphasis is structured toward the processor and we feel this is a result of the emphasis established by the film company representative.

Third, all facilities that were interviewed indicated that frequent training sessions were necessary for all of the x-ray technician staff. The chief technologists indicated that education and training of their staff was probably one of the most important aspects of maintaining good quality radiographs and likewise reduce radiation exposure to the patient. They further indicated that repeats would be more significantly reduced by maintaining and enforcing good quality work by the staff technologists. It became apparent that the majority of repeats would be reduced if the technologists would follow designated technique charts, measure patients accurately with calipers, set the correct technique on the machine for each examination, and properly position the patient.

Fourth, patient exposures could be reduced significantly by using compatible high-speed film-screen combinations and preferably rare-earth systems along with using the highest kVp possible and correspondingly reducing mAs up to the point where the radiologist will not accept the film because of the lack of contrast, noise problems of the film, and so forth. Even the facilities that are monitoring their processors felt that their actions were not significantly decreasing either patient exposure or retake rates within their facility.

Estimated retake rates ranged from a low of 4 percent to a high of 14 percent. A particular hospital has an actual retake rate of 8 percent as a result of a study they conducted. The hospital shoots about 19,000 films per month. They have projected that if the retake rates decreased by one-half (from 8 percent to 4 percent) the cost saving, using a total cost of a retake of $4, will be over $3,000 per month, which extrapolated to over $36,000 per year. If they only reduce the retake rate to 6 percent, the annual cost savings will be over $18,000. We plan to monitor this facility very closely over the next several months to determine the results and accomplishments as a result of their quality assurance efforts.

In conclusion, I would like to mention our plans for the future. First of all, we plan to maintain our concept of using one of our inspectors to proceed full time in quality assurance. If we determine that our efforts are justified, then we will expand our QA training to all of our other State x-ray inspectors. We may then phase in quality assurance with our x-ray inspections.

Second, after this initial data gathering period to determine the state-of-the-art in the real world, we will then place emphasis on attempting to establish QA at large medical facilities, such as hospitals, clinics, private laboratories, and so forth, that do not meet our patient exposure limits or those facilities that have repeated and frequent violations of our regulations.

Third, we hope to establish training sessions and workshops for x-ray technologists that would include educational meetings with individual hospital technologists or meetings with the various districts of the Illinois Society of Radiologic Technologists.

We feel our efforts in quality assurance complement our commitment to patient exposure limits. We are, at this time, committed to QA and we feel our State X-Ray Control Program can be most effective by combining our regulatory program with the service approach of implementing quality assurance.

QUALITY ASSURANCE in an UNCONTROLLED STATE: NEXT and BENT in IOWA

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The title, "Quality Assurance in an Uncontrolled State," might make one wonder if Iowa is out of control and about to crash and burn. That may be true, but we will not go into that. I am here to present Iowa data on past and present participation in the Nationwide Evaluation of X-Ray Trends (NEXT) and the Breast Exposure: Nationwide Trends (BENT) programs by a State that has had no radiation control legislation prior to 1978 and has still not implemented that which was signed into law in 1978 and was to have become effective this year.

The University Hygienic Laboratory has traditionally been involved in doing x-ray surveys on a request basis throughout the State since the early 1960's. Iowa's first involvement with Federal x-ray programs was in the Dental Surpak program. The participation in the NEXT program was initiated when a contract with the Food and Drug Administration to do 100 randomly selected surveys was signed in 1976. The contract was proposed to determine what x-ray exposures were like in a State with no x-ray legislation compared to those States that have had x-ray legislation for a number of years. These surveys were to include 15 hospitals, 25 dentists, 40 MD's and DO's offices, and 20 from other categories. As it turned out, the other categories included 17 chiropractors and 3 podiatrists. Some results of this contract are listed in Table 1 showing a comparison of Iowa data with All-States data. The difference of means could not be validly compared unless at least five surveys were completed and the mean index was within 50 percent of the computed mean index at the 95 percent confidence level. Therefore, no significant differences in exposures were noted between Iowa data and All-States data.

Table 1. Iowa NEXT surveys - representative category

Procedure	No. of surveys		ESE (mR)		Difference of means
	Iowa	All States	Iowa	All States	
Chest (P/A)	59	1289	21.1	19.2	Not sig.
Skull (Lateral)	2	124	334.0	228.0	N/A
Abdomen (KUB)(A/P)	16	509	654.6	591.7	Not sig.
Retrograde Pyelogram (A/P)	2	112	1403.2	724.6	N/A
Thoracic Spine (A/P)	4	25	556.5	814.2	N/A
Cervical Spine (A/P)	14	168	125.9	165.5	N/A
Lumbo-Sacral spine (A/P)	42	637	703.4	735.7	Not sig.
Full Spine (A/P)	4	53	335.9	201.9	N/A
Feet (D/P)	4	75	102.4	254.4	N/A
Dental Bite Wing Posterior	31	1764	564.5	430.1	Not sig.
Dental Periapical	32	761	755.9	428.6	Not sig.
Dental Cephalometric (Lateral)	2	63	162.0	61.5	N/A

Since the termination of the NEXT contract, Iowa has continued to participate in the program by supplying data in the nonrepresentative category. The results of these surveys are shown in Table 2 as compared to the same All-States data. Results of these surveys show that the average entrance skin exposure dose for most of the projections in Iowa is less than for All-States. It was expected that this would be the case since the facilities surveyed were not randomly selected but were those done for the Medicare Certification Program or for those who requested x-ray surveys. The major difference in the Retrograde Pyelogram (A/P) projection is primarily the result of using older equipment in the surgical area that is physically separate from the x-ray department. This equipment tends to be somewhat neglected; e.g., inadequate filtration, slower speed intensifying screens, and poor quality control with the film processor, if it is designated solely for this area.

Table 2. Iowa NEXT surveys - nonrepresentative

Procedure	No. of surveys		Entrance exposure (mR)	
	Iowa	All States	Iowa	All States
Chest (P/A)	82	1289	20.8	19.2
Skull (Lateral)	27	124	151.3	228.0
Abdomen (KUB)(A/P)	71	509	540.0	591.7
Retrograde Pyelogram (A/P)	11	112	1110.8	724.6
Thoracic Spine (A/P)	3	25	423.0	814.2
Cervical Spine (A/P)	12	168	107.0	165.5
Lumbo-Sacral spine (A/P)	54	637	540.4	735.7
Full Spine (A/P)	1	53	70.0	201.9
Feet (D/P)	--	75	--	254.4
Dental Bite Wing Posterior	47	1764	355.6	430.1
Dental Periapical	55	761	363.5	428.6
Dental Cephalometric (Lateral)	--	63	--	61.5

Participation in the BENT program commenced in 1978, when questionnaires were sent out to those facilities that potentially might do mammography. Thirty-six facilities reported that they do mammographic x-ray projections. Thermoluminescent dosimeter exposure cards were sent to these facilities with instructions on how to expose them. These cards were then transmitted with appropriate controls to the Food and Drug Administration for evaluation. Table 3 shows a comparison of the entrance exposure and estimated half-value layer by type of image receptor of Iowa data and All-States data. The mean exposure values in Iowa are less in all categories. The half-value layer is slightly less for Iowa data except for direct exposure film. Table 4 shows the same type of data, but the type of anode material is considered also. The exposure values are less in Iowa for all categories compared, except tungsten targets with film/screen combinations. In that case, it is almost the same as the All-States average value. If one compares the estimated half-value layer (HVL) by nominal kVp with data from Iowa and All-States as in Table 5, one observes the most common HVL for the most typical peak kilovoltage range (26-34 kVp) for all film image receptors to be between 0.5 mm and 0.9 mm aluminum equivalent. Iowa has 10 facilities in this category while All-States has 588 facilities. For xeroradiography, the HVL for the most typical peak kilovoltage range (35-50 kVp) was about evenly distributed between the 0.8 mm to 1.4 mm Al equivalent category and the greater than or equal to 1.5 mm Al equivalent category. in fact, all of Iowa's 15 xeroradiographic facilities were in these two categories. All-States data showed that 1090 were in these categories and 147 were not.

Table 3. Iowa BENT surveys--entrance exposure by type of image receptor (Manual Mode)

	All image receptors		Direct exposure film		Film-screen combinations		Xerox	
	Iowa	All States	Iowa	All States	Iowa	All States	Iowa	All States
No. of valid cases	30	2558	4	262	11	1062	15	1234
Mean exposure	0.66	0.84	0.76	1.92	0.45	0.47	0.78	0.03

Estimated half value layer by type of image receptor

	All image receptors		Direct exposure film		Film-screen combinations		Xerox	
	Iowa	All States	Iowa	All States	Iowa	All States	Iowa	All States
No. of valid cases	30	2412	4	263	11	1075	15	1235
Mean estimated HVL	1.15	1.17	1.55	1.01	0.67	0.80	1.40	1.49

Table 4. Iowa BENT surveys - Entrance exposure and HVL by type of image receptor and type of anode material

	Direct exposure film				Film/screen combinations				Xerox			
	W		Mo W/Mo		W		Mo W/Mo		W W/Mo		Mo	
	Iowa	All States	Iowa	All States	Iowa	All States	Iowa	All States	Iowa	All States	Iowa	All States
No. of valid cases	3	202	1	49	5	576	6	440	15	1084	0	103
Mean exposure (R)	0.65	1.76	1.06	2.69	0.36	0.32	0.52	0.67	0.78	0.85	--	1.70
No. of valid cases	3	192	1	44	5	510	6	400	15	1066	0	101
Mean estimated HVL (mm Al)	1.30	1.05	2.30	0.85	0.84	0.94	0.53	0.61	1.40	1.52	--	1.06

Table 5. Iowa BENT surveys - Estimated half value layer by nominal kVp (mm Al)

	All Film					
	< 0.4		0.5-0.9		> 1.0	
Nominal kVp	Iowa	All States	Iowa	All States	Iowa	All States
≤ 25	0	3	1	63	0	21
26-34	1	158	10	588	2	230
≥ 35	1	28	2	70	2	177

	Xeroradiography					
	< 0.7		0.8-1.4		> 1.5	
Nominal kVp	Iowa	All States	Iowa	All States	Iowa	All States
≤ 34	0	0	0	42	0	3
35-50	0	40	8	450	7	640
≥ 50	0	1	0	9	0	52

The ultimate phase of the BENT program is to accomplish onsite surveys of the mammographic facilities. Thirteen of these facilities have been surveyed in Iowa. A comparison of the results of these surveys with the previous exposures of the TLD exposure cards is shown in Table 6. The similarities of data from the two measurements tend to lend much validity and credibility to the TLD exposure card phase of the BENT program. In some cases, slight changes in exposure techniques may have occurred between the TLD and onsite phases of the monitoring program. The L and H notations were used to identify those items that were low or high relative to predetermined BENT criteria.

Table 6. Iowa BENT surveys

	Entrance exposure (R)		Half value layer (mm Al)	
Facility No.	TLD Card	Onsite	TLD Card	Onsite
01	0.620	0.862	1.6	1.6
05	1.550	1.830	0.5	0.4
12	0.580	0.634	1.6	1.6
15	0.270	0.240	1.1 H	0.8
18	0.230 L	0.293	0.8	0.8
19	0.830 L	1.320	0.7	0.6
24	0.600	0.651	1.6	0.8
25	1.060	1.032	2.3 H	2.3
27	0.390	0.409	0.8	0.7
28	0.100 L	0.121	0.9	0.8
31	0.550	0.553	1.3	1.3
34	0.440	0.541	0.8	0.6
36	1.120	1.390	0.6	0.5

X-ray facilities in Iowa are continuing to improve as evidenced by the number of facilities that have purchased new x-ray equipment since August 1974, and which are now being surveyed as part of the HEW compliance monitoring program. Approximately 1000 x-ray machines have been installed in Iowa since that date. It is hoped that a large percentage of these are replacement units and that their predecessors are retired for good.

Participation in these x-ray programs and interpretation of the results of our data with All-States data has led me to the following conclusions.

Those practitioners who have been in the field for many years and are close to retirement tend to have antiquated equipment and are hesitant to upgrade their x-ray facilities. Many of the x-ray machines in doctors' offices are of World War II vintage. A large number of these machines have cones to collimate the x-ray beam instead of adjustable collimators. Some were found to use their equipment without collimation.

A small percentage of the x-ray facilities surveyed have poor quality control programs for their darkroom. This was evidenced by the fact that sight development was used. An understanding of time-temperature charts was lacking in these facilities.

The hospitals tend to have the best x-ray facilities, because they are surveyed regularly either by JCAH or Medicare; they tend to have more modern x-ray equipment, better trained personnel, automatic processing, and more frequent contact with x-ray equipment suppliers to keep them abreast of recent developments. Also there are more personnel attending meetings that would bring back information on the "state-of-the-art." Where radiologists are used, x-ray programs are generally of higher quality.

The chiropractors tend to have newer x-ray equipment than the MD's and DO's because they have not been using x-ray in their activities for as long and they do not require as sophisticated equipment, thereby making the cost of new equipment more attractive to them.

When carried out in the appropriate manner, the NEXT, BENT and other FDA-sponsored x-ray programs can be an educating experience for the personnel of the facilities that participate in these programs.

DISCUSSION

DR. PROPERZIO: I would like to emphasize one point that I think I see in the data. If I wanted to be the devil's advocate I could say that the data prove we do not need to vote for radiaton control programs because some of the NEXT data that you were showing were less than the States that had control programs. I think that is a false conclusion and I think that a realization that some of the classical things that have been done, checking filtration, checking collimation, strictly going by the regulations that may be on equipment may not be accomplishing the goal. There were things that you were unable to look at because of the systems you were using. What were the repeat rates? What was the diagnostic yield? What was the quality of the film? There are specific things such as these that I think a program can get at and I think the conclusion that should be reached from what you have shown here is that it is time to shift to things that will affect other elements of the diagnostic process.

MR. COCHRAN: I cannot help but agree with you 100 percent in that regard. In some of these things that I mentioned, especially about the radiologists and where they are utilized, the facilities have better quality control, better quality assurance, and I think a lot of it is because they do have strict limits on their image quality that they will accept this type of thing and as a result it really makes the x-ray technologists tow the line a little bit more. I have run across facilities that use a pool of radiologists and it is amazing some of the comments from the technologists stating that this doctor or radiologists wants this type of density and this guy wants them another way. I have mentioned that in these cases they ought to get their radiologists together and determine what is acceptable to all of them and as a result they may be able to reduce retakes. They do have unnecessary retakes because of the difference in preference among the radiologists involved. Another thing I wanted to mention is that I think there is a need for some x-ray legislation. There are some facilities--and it is just a matter of going out into the field, visiting some of these facilities 2 or 3 or more times--that have some of the same problems each time even though they have been made aware of the problems, and for one reason or another they have not corrected the deficiencies. And so from this aspect, there definitely is a need for x-ray legislation and I think it is the big reason why Iowa has finally succumbed to more legislative process. I think that because of the factors I have mentioned, and because the States around us have x-ray legislation, we have gotten interchanges in the state-of-the-art which have tended to upgrade our program over the years. The fact that we have also had at least an ongoing x-ray inspection program of a voluntary nature has helped some too.

THE USE of QA ACTIVITIES in lieu of a REGULATORY HAMMER

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The filter/collimator kits that were assembled for the U.S. Public Health Service in the late 1950's by the dental x-ray machine manufacturers and distributed to the dentists for "self-modification" of their x-ray units were part of one of the first programs for patient exposure reduction that was effective. Some State programs got all excited and promulgated and adopted regulations requiring 1.5-2.5 mm Al equivalent filtration, and a beam diameter of no more than 3 inches at the tip of the spacer cone. Other ridiculous and oppressing requirements, such as reproducible timers with 6-foot cords, lap aprons, diagnostic tubeheads, and lead in the walls soon found their way into rules and regulations. One ultra-conservative State program even had the audacity to write into their regulations a maximum patient exposure for dental bitewing exams.

Similar restrictions were placed on all x-ray uses and users. Entire programs and multi-kilobuck budgets were requested, justified, and awarded based on these regulations that needed to be enforced and required specially trained experts for inspection.

How many of you remember the good old days when you ran your program off a bluff? Remember when you were not encumbered by these detailed, and sometimes redundant regulations that dictated how your inspections were performed? If someone were to ask you today - "What activities do you do to assure or promote sound radiological health practices," can you honestly reply, "Anything I can get away with?"

In our Wyoming program, we have just as much authority to tell a practitioner or technologist that he is using too much technique and is over-exposing his patients as we do to perform an HVL measurement. That isn't all bad!

Prior to my arrival in the Wyoming program in late 1974, Bobby Dillard had decided the State should be involved in DENT. It had been at least 6 years since routine inspections had been performed on any dental units, and this seemed to be a logical place to start.

Phase I showed that we had a distribution of exposures that was not unlike the other States who had tried DENT: we ranged from 10 mR/film (medical unit) to approximately 5 R/film.

Because of a very scattered population and limited personnel and resources, we had to prioritize our Phase II followup visits, and decided to concentrate our efforts on those tubes with exposures greater than 600 mR/film, which seemed to be a pretty good number to borrow from Illinois. We also did some followup surveys on tubes with exposures below 600 mR, but were outside the "optimum range." As you might expect, the majority of the super-high exposures involved the older, 65 kVp machines, and we were not too surprised to find dentists using their radiatized film technique on ultraspeed film. If you expose the new film to 5 R, you only have to "dip and dunk" for 15 seconds to get a readable film. "Ain't modern technology grand!!!"

To make a long story short, within 6 months, after followup surveys on 99 tubes, the distribution shifted downward and we had cut the average exposure per film exactly in half: 651 to 325 mR/film.

J.I. Ingle states in Public Health Reports that during 1969, over 773 million dental procedures were performed in the United States, with 34.7 percent of them involving x-ray exams. If all States have experienced a reduction in patient exposure similar to Wyoming's, think of the man-rems and the associated health risks and costs that have been saved.

We just completed another mailout, survey--Phase III if you will--and as we anticipated, some slippage has occurred. Some of our reformed "dip and dunkers" have fallen off the wagon; however, our high exposure was only 1500 mR this go-around, and the average exposure was only 22 mR above the Phase II average.

This is a major accomplishment, due entirely to QA! Some x-ray users still feel we have a regulatory hammer. We intend to nurture that misconception and run the bluff as far as we can.

We have extended our QA activities into medical x rays as well. The second mailout survey in the BENT program revealed that we still have problems with mammography exams, but this time they are all on the low side. The facilities that had super-high exposures on the first go-around have either switched from direct exposure film to film/screen combinations or have stopped doing mammograms entirely.

We have devised a survey form that is entirely QA. Because I do not have regulations that reqire certain HVL's, I do NOT feel obligated to check the same machine year after year for filtration. On repeat inspections I do a cursory HVL check, but concentrate on other parameters such as:

1. Timer reproducibility and accuracy;
2. Exposure reproducibility;
3. mA station linearity;
4. kVp calibration
5. Darkroom integrity;
6. Patient exposure per exam and comparison between rooms;
7. Processor sensitometry and maintenance; and
8. Technique charts.

Some real problems have surfaced, which everyone thought would be eliminated with the x-ray performance standard:

1. Adjacent rooms in the same facility, which are all certified, may have kV variances of 10 kV or more, as measured with the Wisconsin Cassette.

2. On one new machine in particular, adjacent mA stations are within the required 10 percent of each other, however, if you compare the output of 600 mA with the output at the 100 mA station, they vary by greater than 50 percent.

Can we expect the technologist or the department to know this, and be able to measure output and adjust technique accordingly? Hal Stocks would say, "A good idea, but dreamy." I say, "It will never happen." Somehow additional requirements must be placed on the manufacturer/installer to aid the x-ray user in his efforts to produce diagnostic films with optimum patient exposure.

In conclusion, let me say that QA activities can be used to promote sound radiological health practices. In Wyoming, we have established a level of rapport with the dental profession such that the State Board of Dental Examiners has volunteered to enforce our compliance actions against its members. Unfortunately, the other disciplines have not followed suit.

We cannot say that QA can be used exclusively in lieu of a regulatory hammer, but it can sure help to keep from swinging it so often.

NEXT/DENT COMPARISON STUDY

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NEXT PROGRAM

NEXT (Nationwide Evaluation of X-Ray Trends) is a program coordinated nationally by the FDA's Bureau of Radiological Health in which State radiation control agencies measure x-ray machine output through a standardized field survey technique. This survey procedure allows determination of the radiation exposure to a standard patient and also allows calculation of radiation dose to certain body organs from standard radiographic projections.

Survey personnel from participating agencies visit x-ray facilities and inquire as to the techniques used for examinations on a standard-sized patient (5 ft 8 in, 164-lb adult) for whom the body part thicknesses are listed for the appropriate examination. Additional information is acquired on workload, facility type, and operator training and experience. The operator is then asked to set up the x-ray unit as if he were performing an examination for one of the twelve projections, of which two are intraoral dental projections. Using the information collected in these surveys, the entrance skin exposure (ESE), half-value layer, and beam-area-to-film-area values are calculated. The number of most interest, and hence most quoted, is the ESE in mR; that is, entrance skin exposure, free in air. For dental projections, this is the same as exposure at the cone tip.

The surveys are performed at facilities selected by a random selection process and hence are a stratified statistical sample of all facilities within that State. The sample rate and workload factor are combined in calculating means so that their values are representative of the facility-based universe.

DENT PROGRAM

DENT (Dental Exposure Normalization Technique) is an action program aimed at exposure reduction and quality assurance and is conducted by State radiological health agencies. This program is primarily broken down into two phases:

Phase 1, the screening phase, consists of mailing an x-ray exposure card, with attached thermoluminescent dosimeter, to each dentist or operator of dental x-ray units. The operator is to expose each card, using his customary kilovoltage, milliamperage, and timer settings, for a posterior interproximal (bitewing) examination. These data are to be recorded on the card, as well as machine model, type of film, type of cone, and length of cone. The instructions direct the operator to place the cone over the card so that the TLD chip is at the cone tip. These cards are then returned to the agency for processing of the TLD data, which yields an exposure at cone tip.

Phase 2 of the DENT program requires a decision as to what levels of exposure should be considered high and hence what units should be scheduled for a visit by a surveyor. This is a pragmatic decision that involves not only the exposure level but the manpower available in the program and the number of units that could be visited. The Phase 2 visit involves a more careful examination of the x-ray unit and procedures for processing dental radiographs, and a demonstration by the surveyor of ways of possibly lowering the exposure and improving the image quality. Phase 2 of the DENT program has been highly effective and is certainly a desirable program. However, it is manpower-intensive and may not be possible for some State programs.

The NEXT/DENT comparison being made in this paper involves the comparison of the exposure at cone tip as calculated from a NEXT survey for the bitewing projection and as determined by the TLD's in Phase 1 of the DENT program. This value can be evaluated on a scientific basis and a decision reached as to the equality of the two different surveying techniques.

Survey Data

The question "How do exposure values as determined by DENT and NEXT compare?" has been asked for some time and has been raised by several States. We did not have time to research it until a year or so ago. This project was initiated when one State program compared the DENT values with the NEXT values as recorded over approximately a year of that program's efforts. The DENT values were those obtained in a normal Phase 1 TLD card mail-out to the dental facility operators. The NEXT exposure values were those calculated by the NEXT Program following the State surveyors normal facility visits. These two values were not necessarily obtained within a short time span; in fact, a year may have elapsed between one survey and the other.

The results of this comparison are plotted on the scatter diagram titled "Survey Data" (Fig. 1). As you might expect, this comparison shows a "shotgun" pattern. On this and all following scatter diagrams the central line at a 45 degree angle is that of an exact equality - that is, if they were in perfect agreement, the NEXT value would equal the DENT value and all points would fall on this line. Two lines have been added which show the plus or minus 20 percent values. The upper line on the diagram indicates DENT values are 20 percent less than NEXT: the lower line indicates DENT values 20 percent greater than NEXT. As you can see, there is considerable disagreement between NEXT and DENT values for exposure at cone tip.

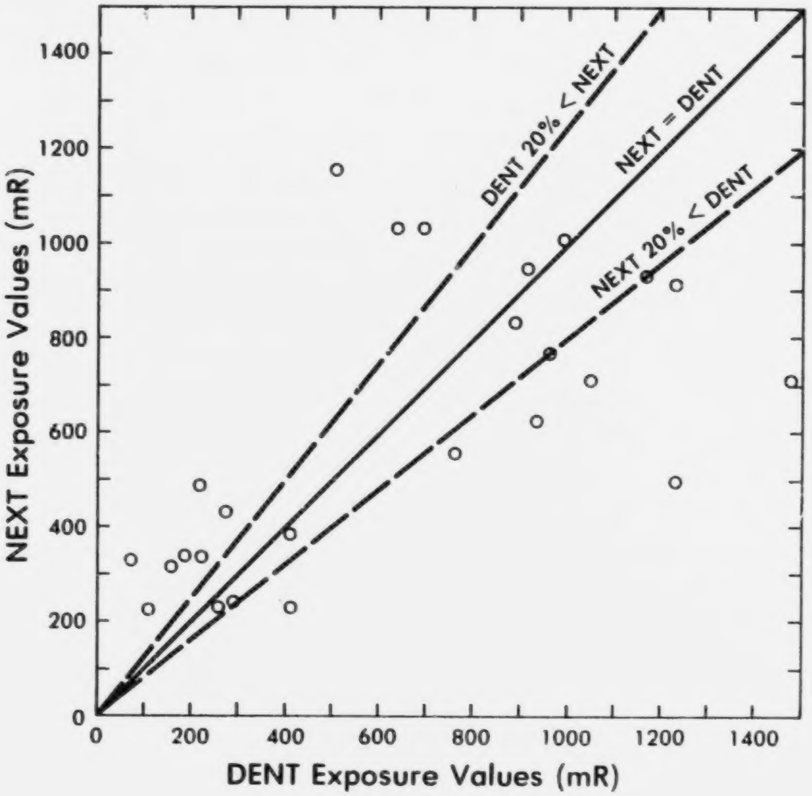


Figure 1

Naturally, there are several possible explanations for this pattern. For example, over a period of time, the technique values may have changed, or different techniques may be used for each respective exposure. In addition, there may have been a change in the output of the x-ray unit itself. Also, the instructions are for the operator to bring the cone-tip down into contact over the TLD chip. At these short target to cone-tip distances, even small differences will result in a significant error. For an 8-inch cone, a 1/4 inch error in target to cone-tip distance results in a 5 percent error in the exposure at cone-tip.

Laboratory Comparison

The wide disagreement observed in the field was, in the least, disturbing. A decision was made to conduct a laboratory experiment for which all parameters were accurately controlled. The DENT TLD chips were exposed with accurate placement with respect to the cone-tip. A NEXT survey was completed using an MDH and accurate application of associated correction factors. The graph labeled "Laboratory Comparison" (Fig. 2) shows the result of this experiment. Indeed, there was some scatter for the TLD's; however, the grouping was extremely small and indicated a slight bias in DENT reading about 11 percent less than NEXT. (Average for NEXT ÷ DENT values = 1.11, with a standard deviation of 0.03 for 10 observations.) Although this difference is statistically significant, for all practical purposes the two values are the same since the NEXT system design includes a possible ± 20 percent and the DENT program includes a possible ± 15 percent. For this experiment the NEXT values for 10 observations had a mean of 658.2 mR, a standard deviation of 1.48 and standard error of the mean of 0.47. The DENT values for 10 observations had a mean of 590.9 mR, a standard deviation of 17.91 and a standard error of the mean of 5.66.

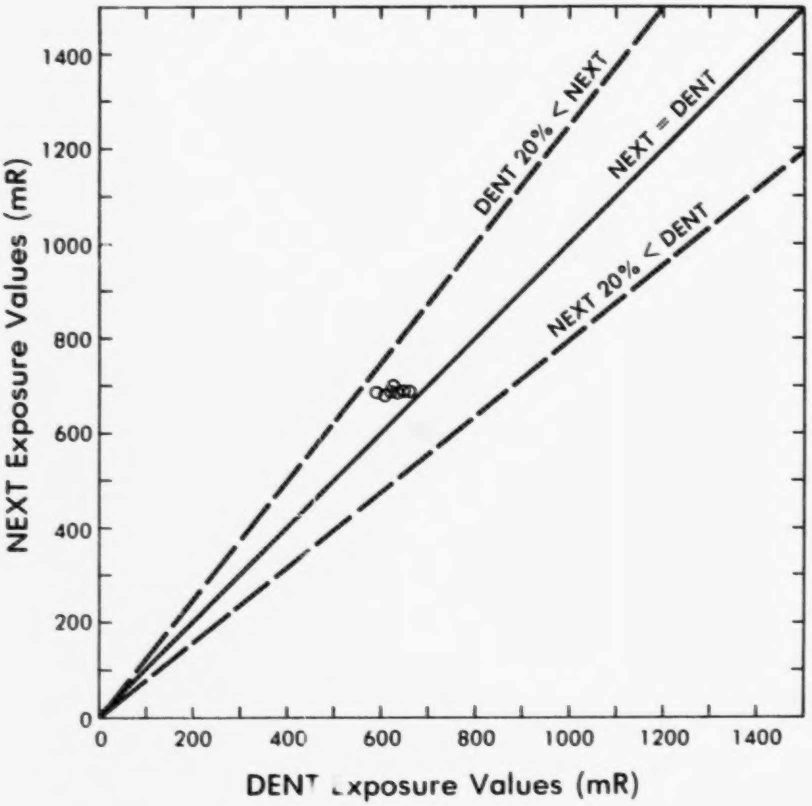


Figure 2

Small Field Test

Two participants in the NEXT program volunteered to expose, under field conditions, a TLD chip in the DENT card, and during the same visit conduct a NEXT dental unit survey. The surveyors were cautioned to pay particular attention to the placement and measurement of all distances and to use the same technique factors for both surveys. After appropriate application of the instrument correction factors (in this case both programs used the Victoreen 666 instrument), the data are as plottted on the scatter diagram labeled "Small Field Test" (Fig. 3). You will note that there is some scatter of points; however, the majority of the values are between the plus or minus 20 percent lines. The average ratio of NEXT ÷ DENT values was x = 0.86, S.D. = 0.23, n = 16 for the program represented by solid dots, and x = 0.96, S.D. = 0.15, n = 11 for the program represented by open circles, indicating NEXT is somewhat less than DENT; 14 and 4 percent respectively. Additional data were needed in evaluating these variations and to determine if these values were representative of a larger number of participants. Hence an effort was made in each of the 10 HEW regions to conduct a similar study.

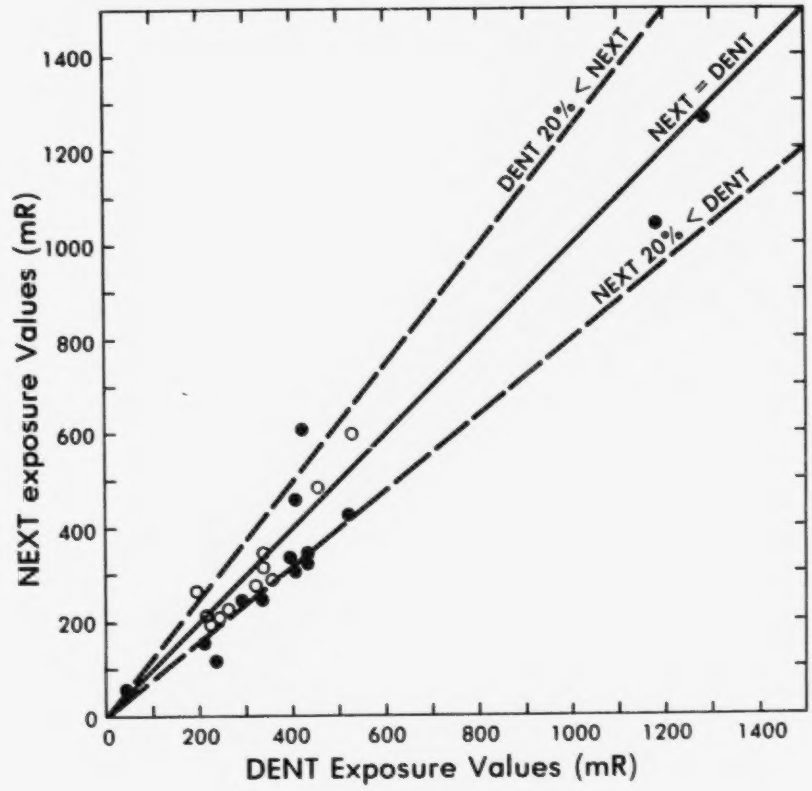


Figure 3

Large Field Test

Twenty-five dental TLD packets were mailed to each of the 10 HEW Regional Offices. Five from each group were to be treated as controls and the other 20 were to be exposed during surveys of dental facilities. A NEXT survey of that dental unit was then to be accomplished using the same exposure techniques. These surveys were performed either by a volunteer State program surveyor or by the EDRO regional representatives. This larger survey thus included various States, various survey personnel, and various types of instrumentation. The results included nine sets of data with various combinations of the previously mentioned parameters.

There were six sets of data produced by individual State programs and three sets of data produced by EDRO representatives. Four sets of data were produced with the MDH instrument used in the NEXT survey, three sets of data were produced with the Victoreen 666 instrument used in the NEXT survey, and one set of data each with the NEXT survey using an LED and a Condenser-R-Meter.

Correction factors were obtained (when possible) for the instrumentation. Non-availability of this correction factor was not felt to be a major problem in the project, since the NEXT uncorrected values are those normally published and used for analysis.

The results of this large field project confirmed the results of the earlier small field project. The numbers have changed slightly, but not significantly. The scatter diagram labeled "All Data, NEXT Instrument Uncorrected" (Fig. 4) appears much the same as the data from the two programs plotted for the controlled small field test (Fig. 3), with the exception that many more data points are plotted. Application of the NEXT instrument correction factor improves the appearance of the scatter diagram slightly (Fig. 5), mainly by reducing the number of surveys with NEXT/DENT by more than 20 percent.

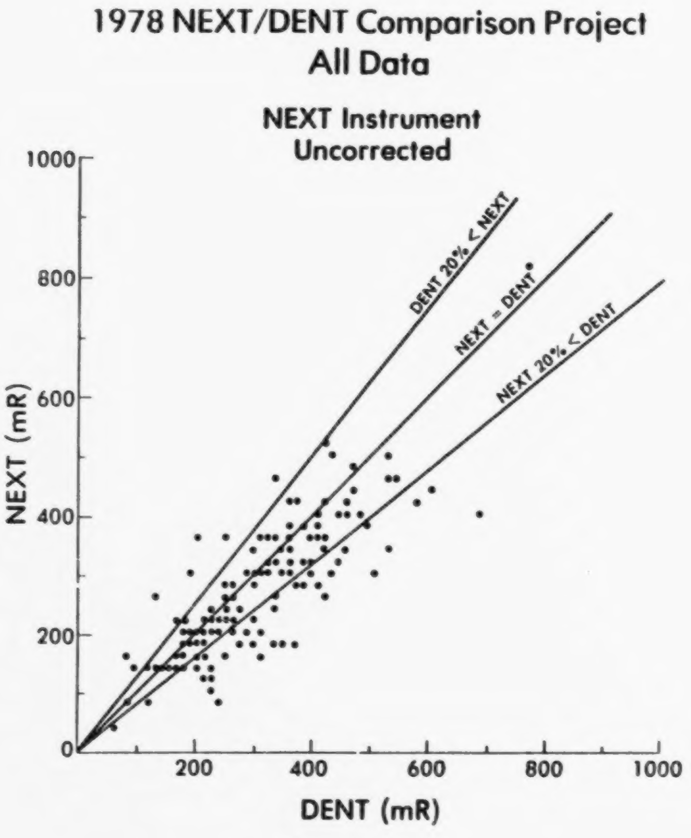
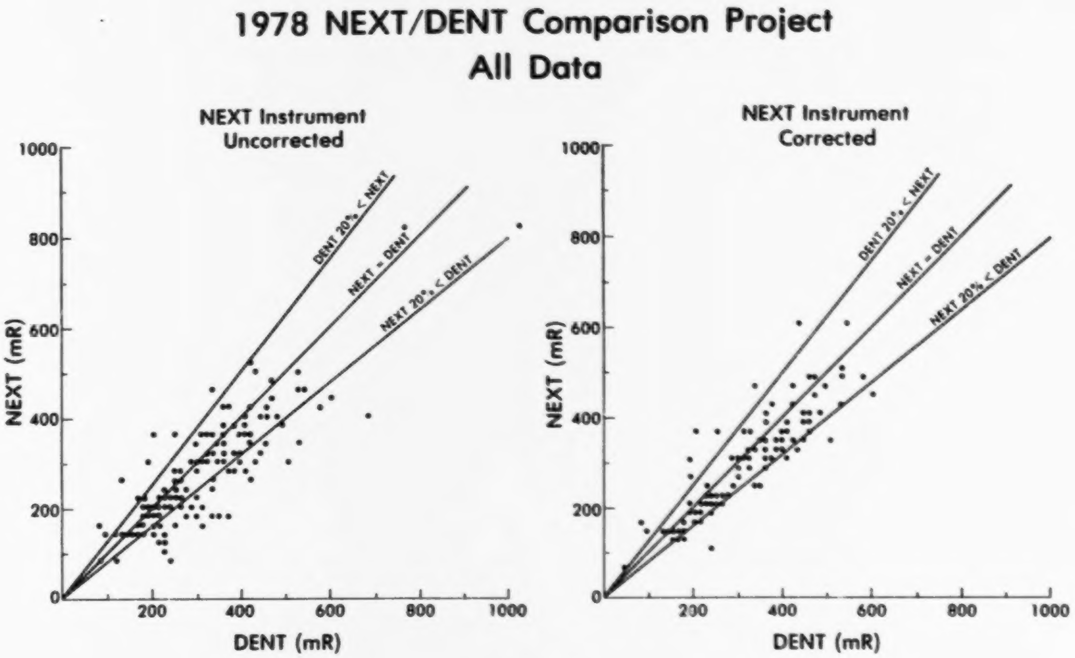


Figure 4



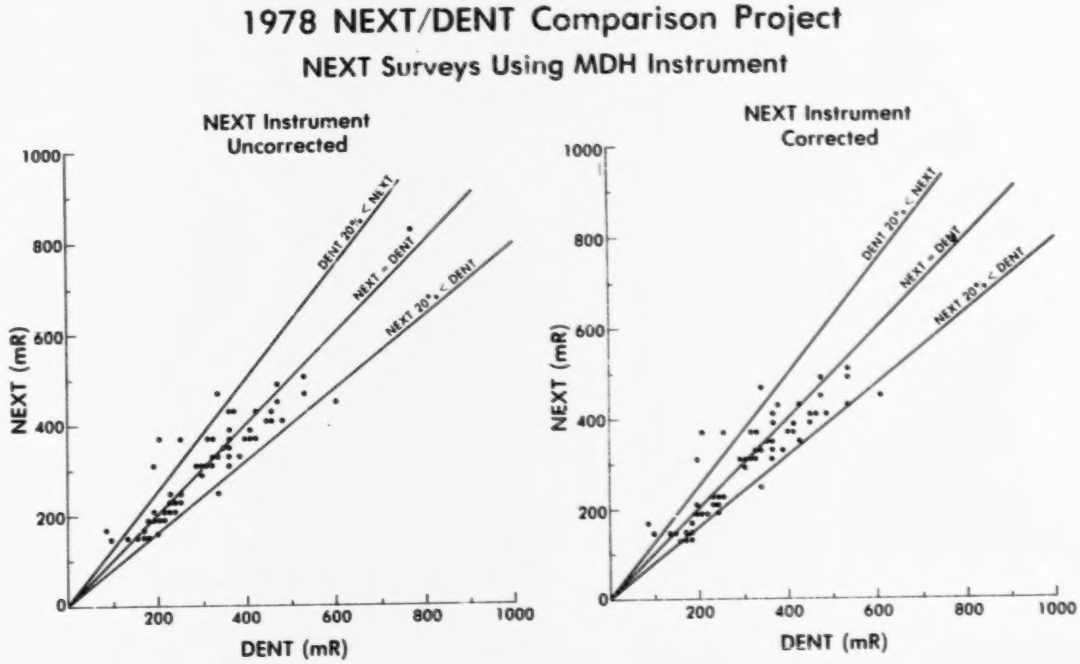
1978 NEXT/DENT Comparison Project
All Data

NEXT Instrument
Uncorrected

NEXT Instrument
Corrected

Figure 5

The data for the MDH instrument alone (see figure labeled "NEXT Surveys Using MDH Instrument," (Fig. 6) indicate a tighter cluster of the data points as well as no significant change in pattern because of the application of the instrument correction factor. No change in pattern was anticipated because of the small correction factors that need to be applied with this instrument.



1978 NEXT/DENT Comparison Project
NEXT Surveys Using MDH Instrument

NEXT Instrument
Uncorrected

NEXT Instrument
Corrected

Figure 6

The data for the Victoreen 666 instrument (Fig. 7) indicate a small improvement with the application of the correction factor. This improvement is both a shift towards the NEXT equal DENT line and a tightening of the cluster.

1978 NEXT/DENT Comparison Project

NEXT Surveys Using 666 Instrument

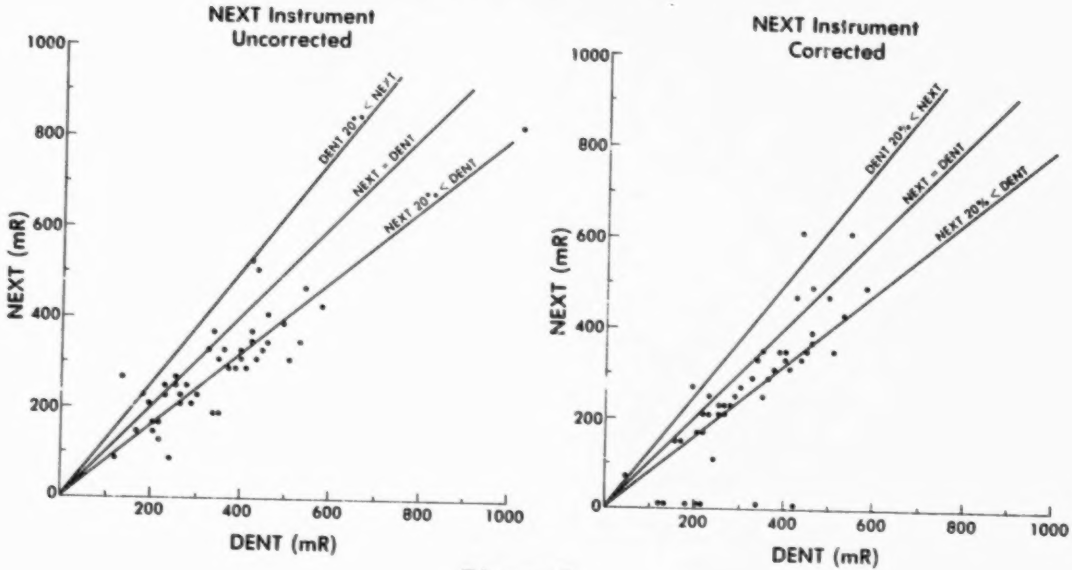


Figure 7

The LED and 2.5 R Condenser-R-Chamber values (Fig. 8) do not appear much different from the Victoreen 666 instrument data. Unfortunatley, no correction factors were available and a comparison of the improvement of the data upon its application cannot be made.

1978 NEXT/DENT Comparison Project

NEXT Surveys Using LED and 2.5R Chambers

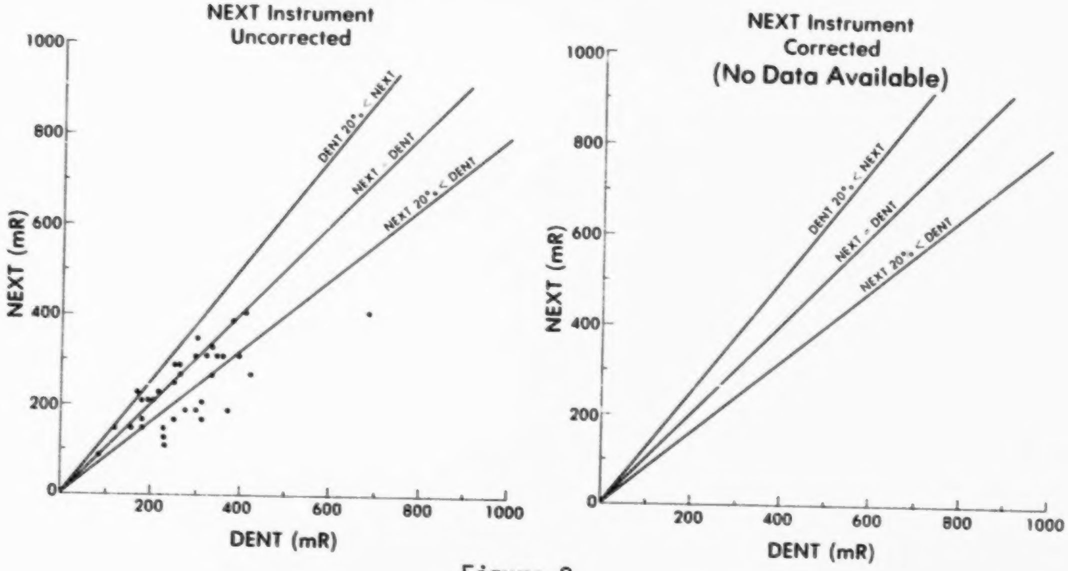


Figure 8

BEST DOCUMENT AVAILABLE

Note the distinct grouping of data points below the NEXT 20 percent DENT line. These data came from a program for which a geometry correction had to be applied because the LED was placed in the wrong position. Hence, one may question the validity of these data.

The scatter diagrams for individual programs (Fig. 9 for uncorrected NEXT values) demonstrate some interesting patterns. In general, the data obtained with the MDH instrument demonstrate a tighter grouping and better agreement between the NEXT and DENT values. However, some programs demonstrate more variation, particularly Programs B and D. Perhaps this is because of the surveyor's technique, or that particular program's control over instruments and/or survey protocol.

Recognizing the effect of typical correction factors (Fig. 10 for corrected NEXT values) for the Victoreen 666 instrument, the scatter diagram for Programs A and G are not surprising. However, the tight grouping of values demonstrated by Program H are unique.

Perhaps the biggest surprise of all is that of Program F (Fig. 9), in which NEXT data were collected using the 2.5 R Condenser-R-Chamber. With the values necessary for an accurate reading on this instrument (requiring multiple exposures) and the possibility of miscalculations when multiple exposures are needed, one would expect a wider variability. This was not observed and, indeed, the uniformity and agreement of the NEXT/DENT values should be envied by other programs.

Program I (Fig. 9) indicates some problem with the scatter of data as well as the overall mean. As mentioned before, there were other problems with the data in Program I, primarily the need for correction because of misplacement of the dosimeter in the test stand. Hence, these data are questionable.

The illustration comparing individual programs after the NEXT instrument correction factors have been applied (Fig. 10) demonstrates no real surprises. In general, those programs using the MDH show only small improvement and those programs using the Victoreen 666 show a slight tightening of the cluster and an improvement of the agreement between the NEXT and DENT values.

The impression that is gained from the data on the scatter diagrams can be expressed in numerical values (Table 1). This table lists the averages of the ratio of the NEXT exposures divided by the DENT exposure, uncorrected and corrected for instrumentation used in the NEXT survey. The ratio obtained using the MDH is indeed quite close to 1.00, which would be complete agreement between NEXT and DENT values.

Another way of expressing these averages is to state that the DENT value is higher by 2 percent for the MDH instrument and approximately 16 percent higher for the Victoreen 666, LED, and 2.5 R instruments. The standard deviation of this ratio for all three categories of instruments is nearly the same, indicating about the same scatter of data points.

For the mix of instruments used in this large field study, it can be seen that DENT values are approximately 10 percent higher. With the application of the NEXT instrument correction factor to the NEXT survey value, there is a slight decrease in agreement for the MDH and a fair improvement in the NEXT/DENT ratio for the Victoreen 666 instrumentation.

One surprise is the lack of improvement of the standard deviation for the MDH and a fair improvement of the standard deviation for the Victoreen 666 instrument. After application of the correction factor, the average for this mix of instruments (excluding LED'a and 2.5 R chambers) indicates the DENT values were 7 percent high.

1978 NEXT/DENT Comparison Project Individual Programs

NEXT Instrument Uncorrected

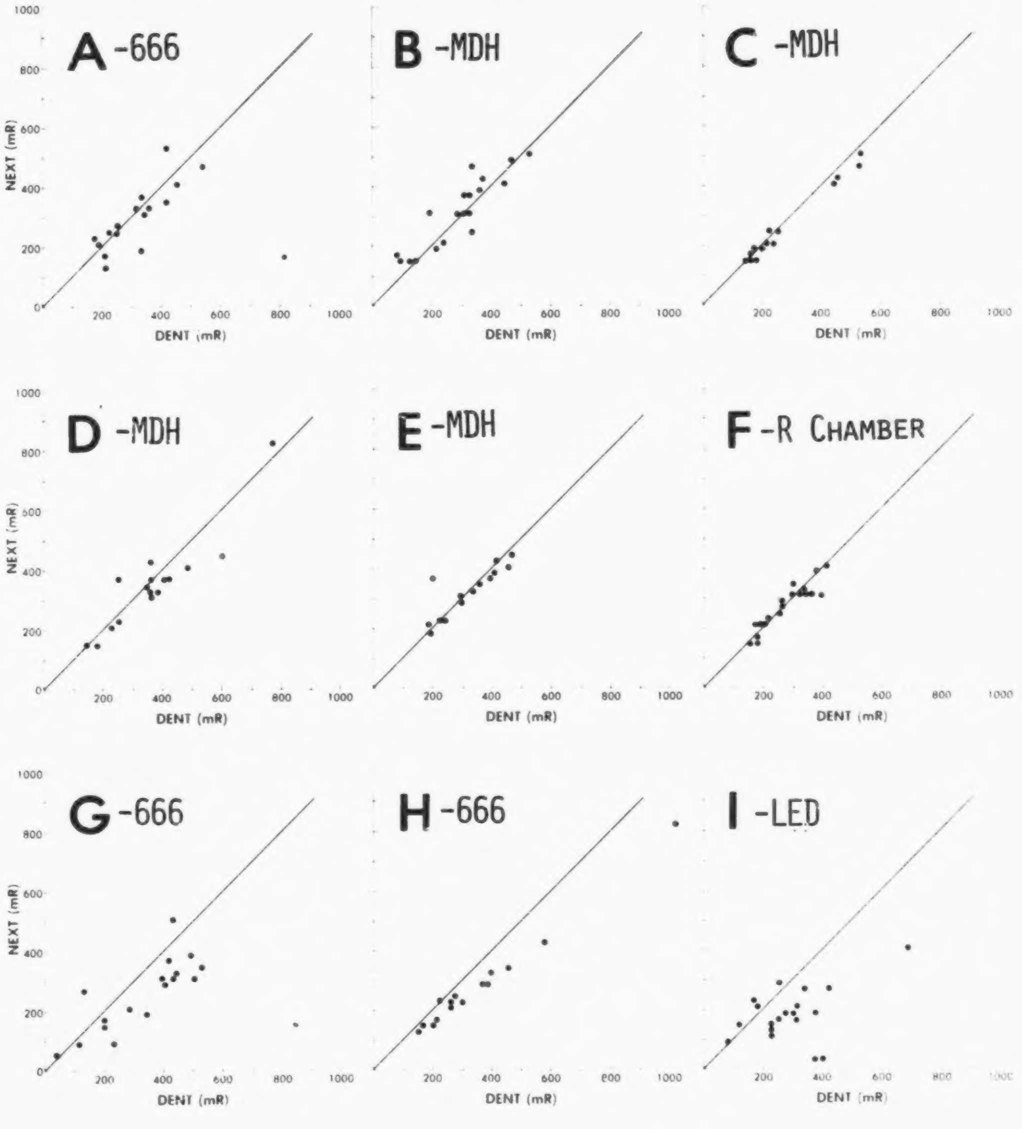


Figure 9

1978 NEXT/DENT Comparison Project

Individual Programs

NEXT Instrument Corrected

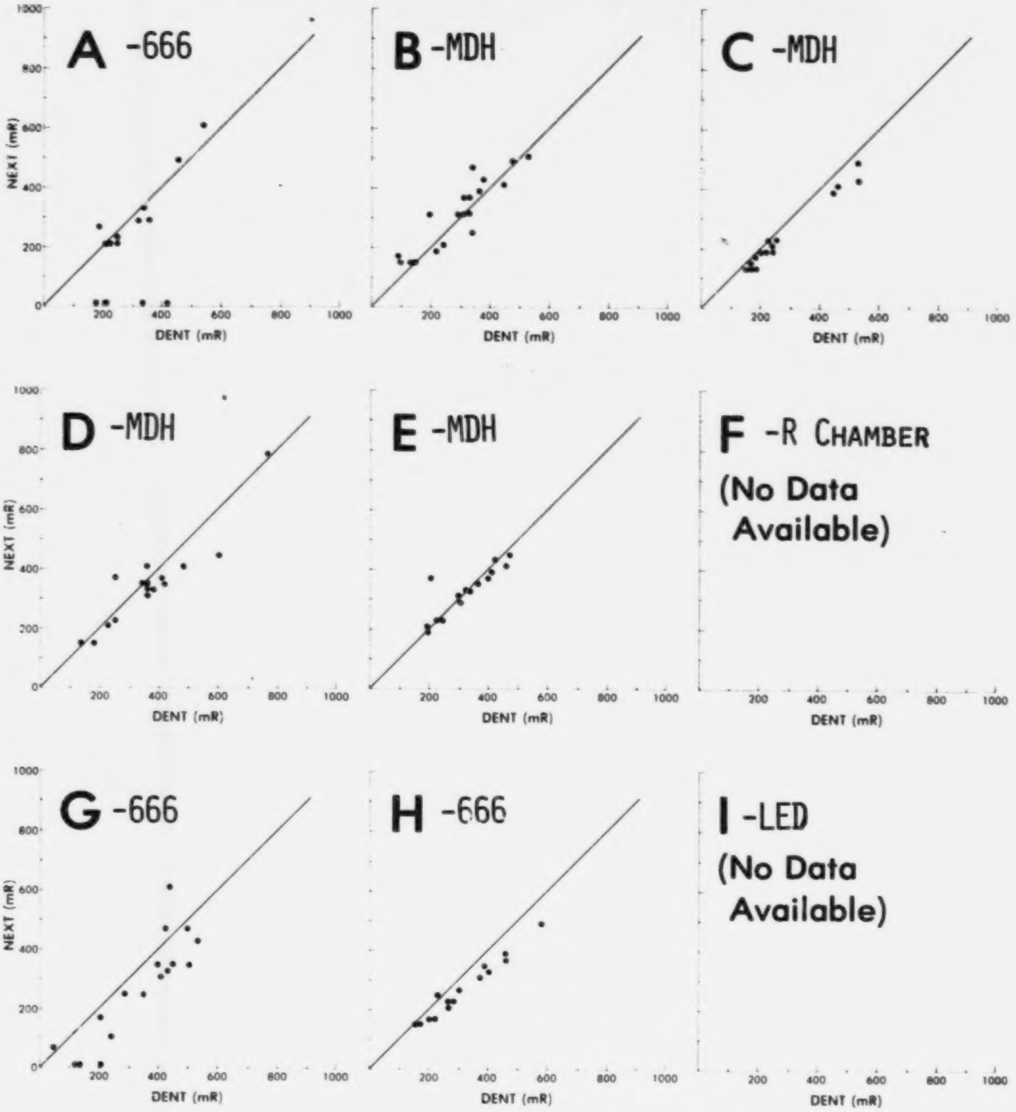


Figure 10

Table 1. 1978 NEXT/DENT comparison project, average ratio of NEXT exposure ÷ DENT exposure

Instrument	NEXT uncorrected Average	S.D.	N.	NEXT corrected Average	S.D.	N.
MDH	0.98	0.22	71	0.96	0.22	71
666	0.83	0.23	54	0.89	0.17	46
Ion chamber	0.84	0.24	38	--	--	0
Total	0.90	0.24	163	0.93	0.21	117

Because of the size of the standard deviations, a statistician would conclude that for a single observation, these differences are not significant. In addition, the NEXT instrumentation is not expected to be better than plus or minus 20 percent, and similar accuracies are claimed (or disclaimed, as you may wish to express it) for the TLD chips in the DENT mailout card.

The bottom line is that there appears to be a slight bias in that the DENT values read approximately 10 percent high compared to NEXT; however, concerning the expected accuracies of the two systems and the demands of a field survey, these two programs are indicating approximately the same value for exposure at cone tip.

A different method of observing this data is expressed in Table 2. If we were to ask the question, "What fraction of the surveys would result with the NEXT divided by DENT ratio being within plus or minus 10 percent, plus or minus 20 percent, or plus or minus 30 percent of the ideal 1.00?" We would conclude that approximately half of the surveys using the MDH instrument were within plus or minus 10 percent. Approximately 80 percent of the MDH surveys are within plus or minus 20 percent. Surveys using the Victoreen 666 would include only about 20 percent within plus or minus 10 percent, and only 40 percent within plus or minus 20 percent.

Table 2. 1978 NEXT/DENT comparison project, cumulative distribution of ratio of surveys within agreement range

Instrument	NEXT uncorrected ±10%	±20%	±30%	NEXT corrected ±10%	±20%	±30%
MDH	0.50	0.79	0.89	0.42	0.78	0.85
666	0.19	0.41	0.81	0.26	0.57	0.78
Ion chamber	0.32	0.58	0.66	--	--	--
Total	0.35	0.62	0.81	0.35	0.69	0.83

Ion chambers (the Condenser R chamber and LED's) show an intermediate position between these two extremes. Application of the correction factor improves the Victoreen 666 data, but has a slight detrimental effect in the MDH-obtained values.

The totals on this table indicate that approximately 60 percent of the surveys show agreement between NEXT and DENT within plus or minus 20 percent. Although application of the corrrection factor improves the overall agreement, the amount is so small that one would question the effort necessary for a large project such as NEXT to accurately apply this correction factor. I must point out, though, that the application of this correction factor is important for individual survey data. Here we are looking at the overall program averages.

CONCLUSION

Although DENT values are slightly higher than NEXT, there is no real difference in exposure at cone tip as determined by the two programs.

The ultimate decision (whether to use NEXT or DENT or both) is more philosophical in nature. Individual facilities are selected by a random selection process in the NEXT program and only a small fraction of the total number of dental facilities are actually visited for a survey. This sampling is done because no program has the resources or manpower to visit every facility in a short time span; by short, we usually mean 1 year. By doing a statistical sample, reliance can be placed on the mean exposures calculated and some information gained as to "what is going on in the real world."

Phase 1 of the DENT program is primarily a screening activity, attempting to collect exposure values for all facilities. Then a decision is made as to which facilities are to be scheduled for followup (Phase 2). The advantage of this procedure is that those facilities giving excessive exposure are identified and the limited manpower is maximally utilized in visiting the higher-exposure facilities.

DISCUSSION

MR. SOURKES: Could you tell me whether you have corrected the DENT values for backscatter?

DR. RUETER: No. The construction of the DENT card with the washer and the aluminum backing was supposedly done in a way to minimize backscatter variation. I have tried to get experiments done to check and find out whether it has really done that adequately or not and as of now have not, but this is an area we plan on looking into.

MR. SOURKES: With the washer there and the piece of aluminum backing you would catch some backscatter.

DR. RUETER: Oh, definitely. What the aluminum and washer are doing is introducing a constant backscatter so that variability from survey to survey would be minor and show little effects of backscatter from whatever they put the card on.

MR. HEIDERSDORF: I assume you are pursuing this for academic rather than practical reasons because I do not see anything very disturbing in that data at all. I do not think it makes much difference and I am amazad at how good it is. So I would say go on to bigger and better things.

DR. RUETER: That is precisely what I plan on doing. When I started out with this project it was sort of "Gee are you going to prove one right or one wrong?" Then when I started seeing this data and looking at it, and I said "What's all the fuss about." But the questions keep coming up and need answering.

USE of BENT in OKLAHOMA

William M. Kemp
Occupational and Radiological Health Services
Oklahoma Department of Health

(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

It is a basic fact that breast cancer is a leading cause of cancer deaths among women today. There is an estimated 90,000 new cases of breast cancer diagnosed each year. Of this number, about 35,000 deaths are involved. As a matter of fact it is a leading cause of death for women between the ages of 40 and 44 and the second leading cause of death for women in all other age groups. So it is a significant problem and because of a very high incidence of breast cancer and its attending mortality rate it is imperative that you have early diagnosis and, hopefully, early treatment. That is the only way that this mortality rate is going to be reduced. From what I know and from what I have read about it, probably the best modality available today for the detection of breast cancer, is mammography.

I would not even presume to suggest who should have a mammogram done, that is not my job. But HEW has some things on how it should be done and of course mammography cannot be done without x-ray exposure to the breast. That is what our job is all about. Mammography is being done, done every day, and that is what we are concerned about. Basically the context of my paper is how we use the BENT program in Oklahoma to try and optimize exposures and image quality. For quite a while now there has been considerable adverse publicity surrounding mammography. It is a frequently performed diagnostic procedure that involves a variety of image receptors and techniques.

Public awareness and concern really began to heat up in Oklahoma about 1976 or so. The general public was becoming aware and starting to show concern regarding the amount of exposure administered to the breast during this specific type of procedure. It was not only happening in Oklahoma, it was happening nationwide; it was a nationwide concern.

Prior to 1976, or really 1977, our diagnostic x-ray division here in Oklahoma had a somewhat loose survey technique for mammography procedures. We were mainly interested in exposure. We had some information or guidelines to go on because of the contact we had made with Dr. Eugene Derso, who is a prominent radiologist here in Oklahoma. We had a working relationship with him in that he explained some of his techniques. We had been measuring dose and we found out that he was getting a real good quality image. He had his own phantom. I cannot remember the name of the phantom, but he had worked with Eagan and he had had it for quite a while and it was a good one. We knew that he was getting a good image with a relatively low dose. So that is kind of what we based whether or not a facility was doing good mammography as far as exposure went. That was the only parameter we were concerned with. It was a loose survey technique and we had no way of making evaluation of the image receptor and their resultant images.

As everyone knows, there are several different image receptors being used and everyone has, each and every one of them has their staunch proponents. It is difficult to obtain agreement among these practicing radiologists as to what constitutes good image. They all have their own ideas, rightfully so, and they know what they want to see and how they want to see them. But it makes it difficult to establish optimum exposure guidelines for any given mammographic image receptor system.

It was hoped that if enough data were gathered on a nationwide basis on the status of mammography that some recommendations would be possible in respect to optimizing the exposure and the image. It was this hope that led to the development of the BENT program. Basically the BENT program was a mammographic quality assurance program and more correctly an exposure or image quality assessment program. It was designed to begin the process of optimizing exposure and improving image quality in the diagnosis of breast anomalies. It was established by the Bureau of Radiological Health with the financial support of the National Cancer Institute. I would like to give some recognition to some State people for the development of this program because it is my understanding that the early investigation into the practice of mammography was made in the eastern part of Pennsylvania by Mr. Henry J. Bicehouse. It seems to me that the emphasis of his study was what really thrust, or at least led to the development at the Federal level of a nationwide program and I think he and his study should be duly noted.

There are four specific objectives to the BENT program: to determine the ranges of patient exposure resulting from the various techniques used in mammography, to determine the causes of unusually high or unusually low exposures, to reduce exposures that are not productive, and to improve image qualities through technique improvement.

We began the BENT program in 1977. Phase I basically is an identification of all the facilities in the State that are doing mammography. We are fortunate here in Oklahoma because early on Bob Craig established a computer program and all our facilities are listed in a sequential listing. We had a good idea as to who was doing mammography because they were listed by clinics, OBGYN, hospitals, and so forth. We sent a questionnaire to everyone that we thought could possibly be doing mammography in the State of Oklahoma. We think that we identified 100 percent of those facilities. Now all we have to do is update it.

We sent all these people, after we identified them, a letter of inquiry asking them basically what they were doing; if they were doing mammography. If they responded to it affirmatively, we asked them some other questions and we asked them for all the information we could possibly think of. Some of them we did not even need. Within a 6-week period, we had this information back. It is funny, when people are doing mammography, it is very easy to find out who is doing it in the next town; they are very anxious to tell you for some reason. We would call up a county and talk to the Chief Tech at the County Hospital and say "Do you know of anyone else in the County that is doing mammography?" and he was very willing to give us that information.

At the end of this phase, we knew the following: we had 46 facilities, we had 50 units and only 2 of the units were phototype, we knew that there were 2,245 patients done in the last month of that year, we knew that the same month of the previous year, 1976, there were 1,550. This represents a 62 percent increase despite the controversy going on. Also, we found out that 29.1 percent of the patients that had mammography procedures done on them in the State of Oklahoma were under 50 years of age. We knew that there were 30,206 patients who had mammographies in Oklahoma in 1976 and I projected that on, just roughly we figured in 1977 it increased to 48,900--approximately 30 percent. So the controversy was not keeping people from getting mammography done and I personally am glad of that because the price to pay for not diagnosing a breast cancer is just too high. There has always got to be some trade-off.

Then the Phase II is when you get the information back from BRH, Rockville, Maryland, and they give you a list of facilities that you should followup with a Phase III type survey. We did have every facility in the State of Oklahoma participate in our program. We had 100 percent compliance. One facility refused to expose the card for us but we were able to collect the data ourselves in our routine inspections.

At the end of Phase II, we knew the following: that there were 44 of the facilities that did both cranial caudal and medialateral views, 21 facilities did 3 views with the addition of an axillary; and that 2 facilities did other views, I do not know what they are. We knew our target types, broken down by machines, someone would go through that. There were 41 general purpose units. I think that is important, only 9 special units in Oklahoma. The receptors used, 26 were film screen, 22 were Xerox, two of which did both positive and negative modes and the direct industrial film technique, there were two facilities done. So at the end of that phase we had our information for the followup survey, our onsite inspection.

When we got our information back we had 13 units or facilities that had exposures that were too low and that was the first surprise to me. We had two that had high exit exposures and the two high ones for both exit and entrance were our two facilities that were doing direct film techniques and that was the easiest thing to correct. The only half-value layer problems we had were one that was too low and four that were too high. Our indicated kVp was too high in three units and too low in two units. But this is the area where the cards do not tell the whole story. We had one atypical processing which I never really understood. I would just like to thank the people in Rockville, like Penney Butler who came down here two or three times to help me get off the ground and loaned me some equipment. When we started Phase III, here is how we differed from the other States that are in the program. As far as I know, I do not know of any other State that is doing this. We decided that instead of doing the problem-survey type, in other words the ones that the Bureau said that we should followup on, we decided to treat each and every facility in the State of Oklahoma with a Phase III followup, an onsite inspection, using the same identical procedures you would use for a so-called facility that was problematic. We found some things that just did not jibe with what should have been. We also decided to do a kVp determination on every unit. And we did so with the Wisconsin Test Cassette for Mammography that is supplied to us by the Bureau (Penny supplied it, I think there are only three of them around). We have not completed Phase III yet because we have a system in Oklahoma where there are three inspectors for the whole State; we have 77 counties. When we go do a county, we clean up the whole county and move on.

I anticipate that we will be finished with Phase III, or we will have made onsite surveys to all our facilities by probably January. We have probably seen 70 percent of them. I have some comments based on the surveys of 10 facilities that were recommended for followup and 10 surveys that were not recommended for followup. The biggest problem we had from Rockville was that they said we had poor image quality because of our low entrance exposure, but also we found out when we did a kVp that the kVp's were way off. We did not have too many filtration problems; I was kind of surprised. I think probably what happened with this low entrance exposure is that most of the radiologists and people concerned in the field were already concerned about the high dose and they were already trying to do something about it. They reduced their dose but their images were poor because of some other problems they had.

The two problem surveys which were concerned with high exposures were because of direct film. There were two hospitals, and we talked to them and asked them to go to another image receptor system and after we showed them their dose (8 R per exposure), they were very glad to do so. That was the easiest problem. The most surprising findings in the Phase III survey is the fact that 75 percent of our surveys indicated the kVp was way off. It was particularly bad when it was associated with the general purpose machine using tungsten target film screen techniques. It is my belief that unless these unit's generators are modified, they are simply not capable of getting down to 28 to 32 kVp range, and none of them are. At least most of them have not had this modification made to their generator.

On the measurements of the kVp on those general-purpose radiographic machines that were indicating 28 to 32 kVp, we found the average at the range was as high as 38 for film-screen systems and one went over 50. So you can see the problems we had with the kVp. We were able to help them out temporarily by adjusting their meters when possible but we were not too successful with that. We just recommended they have their instruments recalibrated. We had fewer kVp problems with the Xerox machines because they use the higher kVp and it does not seem to be as critical with Xerox as it does with the film-screen. You get into your film-screen, using your more sensitive films and you really start losing contrast. Just a couple of kVp's would make a lot of difference. Exposure looks fine and everything but put the image up there you cannot see anything.

Just to sum it all up, the same problems existed in the facilities that they said there were no problems; kVp problems still there. The exposures looked fine, the half-value layer looked fine, but they are losing contrast because of this higher kVp than indicated and their images were just terrible. I think the BENT program is a good one. It is a good one because it is something you can do something with right away. But I think that all of the facilities should have a Phase III followup. I know this will be a problem for some States that are not like Oklahoma and I am sure there are some States that have more units in one town than we have in the whole State, but I think it really should be seriously considered that you do a followup survey on each and every unit. I think that all units, especially those general purpose radiographic machines should be calibrated at least twice a year. I think that the x-ray technologists who are doing mammography procedures should definitely have some specialized training because some of these people were not even aware of what distance they were shooting. You would ask them about the type of target they had and they had absolutely no understanding of tungsten or tungsten-molybdenum or molybdenum. I just found that the techs in Oklahoma with the exception of those in our larger hospitals who had health physicists and who had three or four radiologists on the staff, they just simply could not cut it. They were not there. So the technicians need more training.

Just one last item; I do not believe it is possible to solve the problems associated with mammography unless an onsite survey is made. I think that the survey techniques developed by the BENT program are adequate and are as good as any that I know. I think that if you will just go ahead and instead of saying I will just do those facilities that BRH told me to do because of a specific problem--if you will do them all, you are going to find out the same things I did--that the kVp problems do not show up on the dosimeter cards. They are not there. You have got to get the information in the field, and you have got to get it by measuring the kVp other than that.

DISCUSSION

MR. McHARD: You are saying that this kVp is very critical. Would you be a little more specific and tell us precisely how critical it is with numbers and what number is the cut off and so forth if you have that kind of information?

MR. KEMP: I did not do enough surveys on specialized units to really know. But with the general purpose units with the tungsten and tungsten molybdenum target, 2 kVp can be very significant. If it is supposed to be 30, and you have 32, or you have 32, and you are reading 34, you completely lose your contrast, your scale is just gone, you cannot begin to see the fine granulation or small calcification. You can see maybe the third largest bead and by that time the tumor is probably not in situ anymore, it is metastatic, and you are missing a lot.

A 2 kVp difference is critical when you are talking about ranges between 28 or 32, unless you have a good quality control program going where you have a phantom at your facility, you are taking the shot at least once a week, and seeing what you have and know what you are looking for and unless these machines are calibrated, I would say they have to be calibrated at least twice a year. It is very, very critical.

PATIENT EXPOSURE REDUCTION by "LIMITS"

Dale E. Gergely
Division of Radiological Health
Illinois Department of Public Health

As most of you know, Illinois has taken a unique approach to patient exposure reduction by promulgating exposure limits for some medical and dental procedures.

For the benefit of those of you who are not familiar with our exposure limit concept, let me start by giving you a brief history or our rationale for establishing these limits and our methods of implementation. In 1969, our Department began accumulating specific patient radiation exposure data. These data were derived from regulatory inspections of medical and dental radiation facilities throughout the State.

We noted that radiation exposures varied as much as tenfold for the same x-ray examinations. In an effort to reduce the high exposures and yet not interfere with the desired objectives of the examinations, we decided to establish the limit at the median 75 percentile level. This was rationalized by the fact that if 75 percent of all medical and dental facilities could accomplish a quality radiograph, then the upper 25 percent could change their radiographic process to meet this criterion.

I might also mention, in addition to establishing the mandatory limit at the 75 percent level we also established a recommendation at the 50 percent level for each of our regulated exams. The regulations took on the familiar "shall" and "should" form with language to that effect included in appropriate compliance letters.

Our dental bitewing exposure limit became effective on January 1, 1973, and was based on approximately 3,000 measurements. Two years later, on January 1, 1975, the four medical radiographic examination exposure limits became effective. These exams--abdomen (AP), skull (PA), cervical spine (AP), and lumbar spine (lateral)--were chosen, since the direct beam particular to these studies routinely impacted either on gonads or other critical organs. Approximately 4,000 measurements were analyzed to establish the mandatory limits. Today our computer data base consists of over 40,000 individual patient exposure measurements.

I think it is important to note that the medical exposure measurements were conducted by using a standard reference point. The radiation measurement device (LED & MDH) was placed directly on the x-ray tabletop. Therefore, our measurements do not reflect actual incident exposure to an average-sized adult patient. By standardizing the measurement procedure, we have not altered the geometric factors. We have, however, provided ourselves with an accurate "yardstick" to compare exposures.

With this in mind, I would like to spend some time discussing results and our experience with this approach to minimizing unnecessary radiation exposure to the patient and operator.

Figure 1 graphically depicts the success of our bitewing limit. The data represent results from more than 13,000 exposure measurements. As you can see, through the first quarter of this year, the average exposure for a bitewing exam has been reduced by 49 percent, or more than 300 mR per exam since the bitewing limit became effective in 1973. The 75 percent level has dropped more than 600 mR since it was first established. By multiplying these reductions by facility workloads and summing the results Statewide, exposure reductions approaching the gigaroentgen range are obtained.

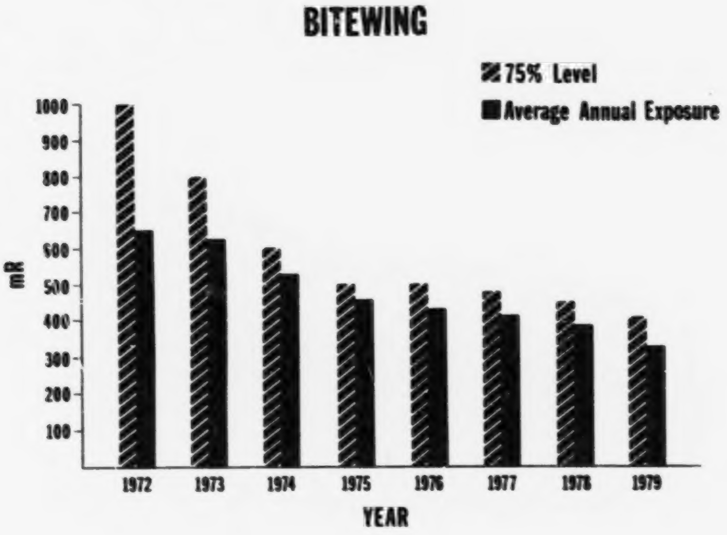


Figure 1

Results of the four medical exams show similar reductions though not as dramatic as those in our bitewing data.

Figure 2 represents 8 years of abdomen data including more than 6,500 measurements. An average exposure reduction of 30 percent has been realized since we started collecting data. The 75-percent level has dropped 400 mR, or approximately 35 percent, since 1972. Twenty percent of the drop was realized during 1975--the first year the limit was effective.

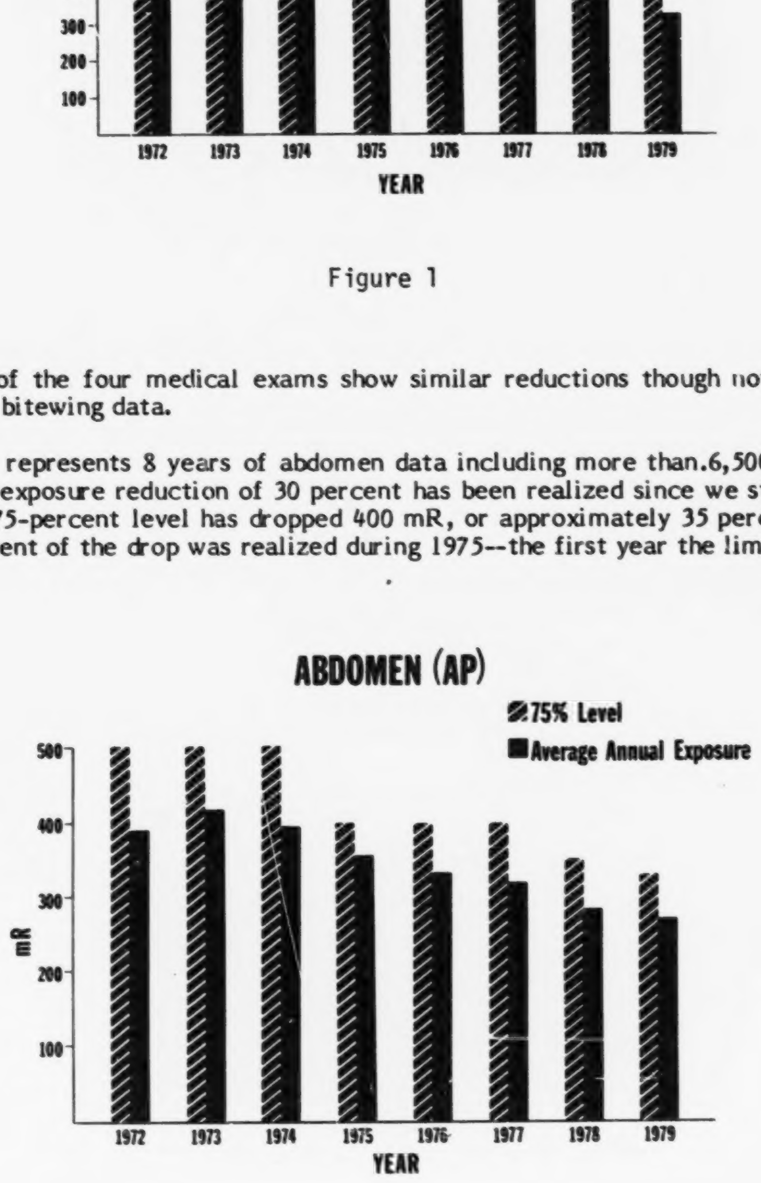


Figure 2

Figure 3, lumbar spine, shows a steady decrease in both average exposure and 75 percent level. The patient who could expect an exposure of 1,756 mR in 1972 can now expect an exposure of 850 mR for the same lumbar spine exam--an average exposure reduction of 27 percent. The 75-percent level shows a reduction of 400 mR. The results in Figure 3 are based on more then 5,000 measurements.

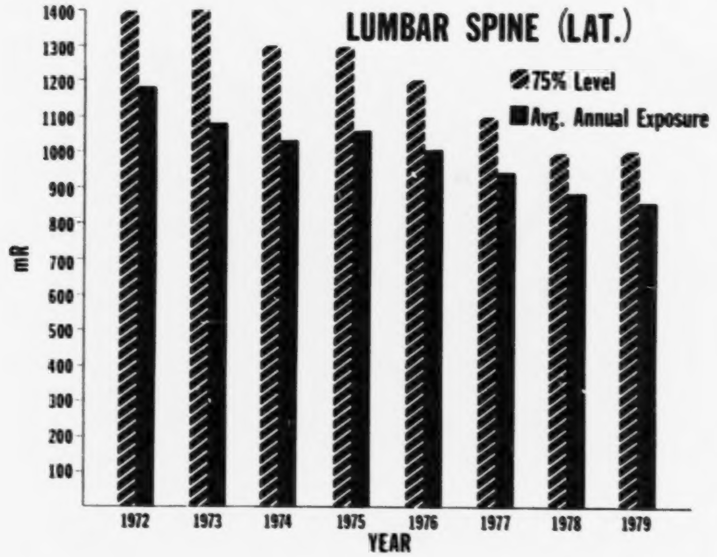


Figure 3

The cervical spine data in Figure 4 show the leveling off in recent years which we expected to see in the data for each exam. The 75 percent level has decreased 44 percent to its present level of 113 mR, while the average seems to be leveling off at around 95 mR per exam.

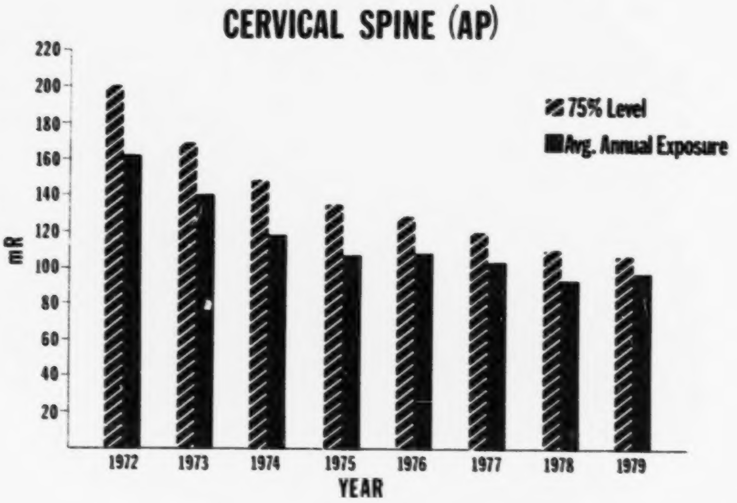


Figure 4

Figure 5, while showing overall reductions in both average and 75 percent level, is much more erratic from 1972 through 1977. This was caused in part by system coding errors, which we hope have been corrected. More specifically, cephalometric, special procedure head studies, and dental panoramic measurements were previously entered into our computer system, for lack of more appropriate codes, as skulls. However these were altered in 1977. You can see a significant change in the data in 1978 and 1979 as a result of these coding changes.

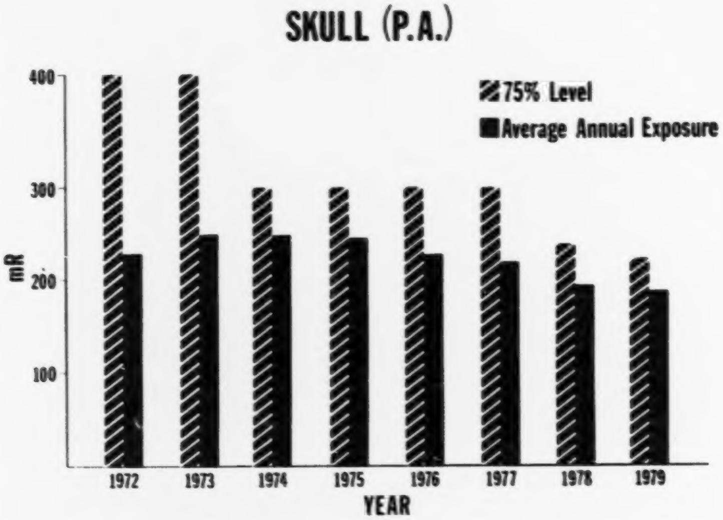


Figure 5

After looking at the results for the four regulated medical exams and dental bitewing exam, at least two questions come to mind. First, how did we attain compliance with our limits and second, how much of the demonstrated reductions were due to our regulatory efforts?

To answer the first question, let me start by explaining that all of our x-ray inspectors are registered radiologic technologists. This means that they come to us with an in-depth working knowledge of x-ray equipment and other factors related to producing a quality radiograph. They are given additional on-the-job training in health physics by our Central Office staff. We feel that, armed with this type of training, our staff is well suited for the job of explaining, educating, and promoting our exposure limit program.

The approach employed at a particular facility to attain compliance with our dose limits depends on the situation. All the facilities, for example, that exceeded the bitewing exposure limit were able to reduce their exposure by either using a higher speed dental film, or by altering their film processing to an adequate time-temperature method, and adjusting their technique factors. Within the past 6 years, in response to this regulatory effort, we have received positive support for the exposure limit approach from numerous dentists and professional societies. Many dentists have not only complied with the exposure limit but have also indicated to us that their radiographs have been improved significantly. We have not received any adverse reaction from licensed practitioners other than those few who seem to always oppose any and all regulatory action involving their practices. We have found that our greatest task is to educate the practitioner and demonstrate to him that he can achieve a high quality radiograph and yet reduce the incident exposure to his patients by a significant factor. We are not aware of any dentist who has had to purchase a new x-ray unit in order to comply with our exposure limit. Even the low 50 kVp units are adequate if the procedural techniques are refined and properly followed. These results are similar to those reported by other States involved in the DENT Program--the big difference being the DENT Program is voluntary, whereas our exposure limit is mandatory.

I will have more to say about our bitewing experience in a few moments--with some comparisons we think you will find interesting.

Achieving compliance with our medical exposure limits required a slightly different approach than those used in dental. The medical exposures that exceed the limit are primarily reduced by increasing kVp and reducing mAs accordingly. Approximately 70 percent of the medical machines exceeding the limit were converted by this method. The remaining 30 percent required a combination of adding filtration in the direct beam and/or using higher speed film or higher speed fluorescent screens. Film processing is not normally a problem since automatic processors are routinely used except for private office type facilities.

Unlike the bitewing limit, achieving compliance with our medical limit did on occasion require spending some money. However, in most cases it was cost related to auxiliary equipment such as faster film or screens rather than new x-ray equipment. These changes could often be made within existing facility budgets by substitution rather than by addition as a new and unexpected item.

To answer the second question, namely, how much of the reported reductions are a direct result of our regulatory efforts, allow me to state the obvious. The reported data are not from a controlled laboratory setting where most of the variables are controlled. We would like to believe that we were the major motivating factor in achieving the reductions. We know, however, that technology, including equipment, is improving along with other factors all of which have an effect on exposure reduction. We must, therefore, look to indicators such as changes in noncompliance rates over the years which perhaps might support our claim. Such a comparison shows that our bitewing exposure limit noncompliance rates have in fact decreased significantly. In 1973, we had a 25-percent bitewing exposure noncompliance rate in dental offices. By 1978, it was reduced to 3 percent. Medical exposure limit noncompliance rates have shown similar results starting with a little less than 25 percent in 1975 and today approaching 5 percent.

We also decided to take a look at overall increases in kVp and corresponding decreases in mAs for a given exam. Results for lumbar and cervical spine are included in Table 1. As you can see, the expected was demonstrated, though not to the degree we anticipated.

TABLE 1: Comparisons by Year and Region for Mean kVp, mAs, and Exposure.

LUMBAR SPINE (LAT)

	MEAN (kVp)	MEAN (mAs)
1972	86.51	221.03
1975	87.58	202.27
1978	88.41	178.74

CERVICAL SPINE (AP)

	MEAN (kVp)	MEAN (mAs)
1972	67.70	52.44
1975	71.05	37.43
1978	71.53	33.19

LUMBAR SPINE (LAT)

	MEAN (mR)
Region 2A & 2B	1056.79
Region 1A, 1B, 3A, 3B, 4 & 5	965.36

One additional comparison; namely, how exposures in the greater Chicago-land area compare with those in the rest of the State. We were interested in this comparison because Chicago-land has never had adequate manpower to visit the many facilities at the frequencies we were visiting facilities in the rest of the State. Results here for lumbar spine indicate that the average exposure is in fact higher in the less stringently controlled Chicago area (Regions 2A and 2B). This fact also supports our claim as the major motivating force behind the exposure reductions.

Results from the top of Table 1 lead us to look into exposure distribution within a given kVp range. Figure 6 shows what we expected to see. For example, of all the exposure measurements in our system entered for units operated at a 100 kVp, a higher percentage of measurements should be at the lower mR ranges as compared to those measurements entered at 70-kVp level. The 70-kVp line should, in turn, be higher at the higher mR ranges as compared to the 100-kVp line. Figure 7 is a plot of the data we actually have in our computer system for lumbar spine. You can see, with some imagination, that what we expected to find did in fact appear.

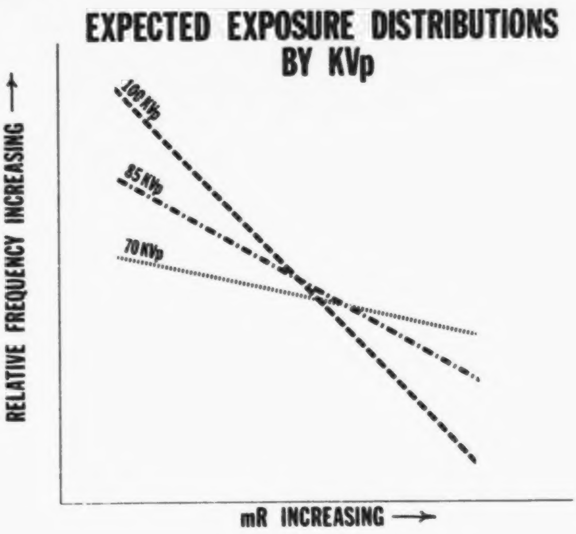


Figure 6

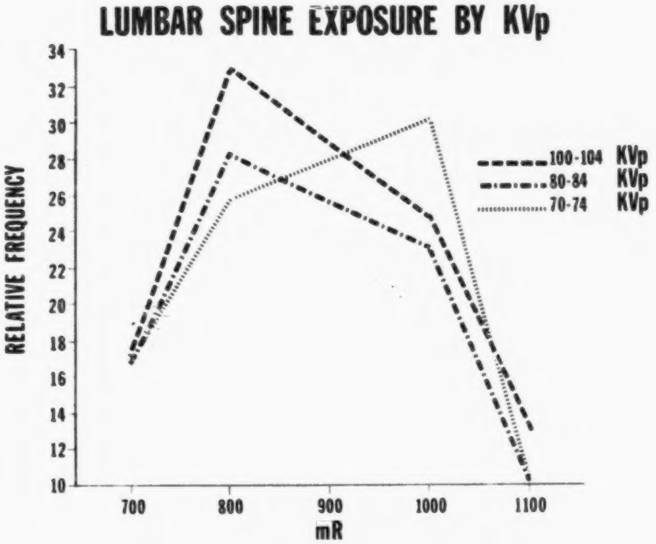


Figure 7

As we got into comparisons of this type we found ourselves coming up with different manipulations of the more than 40,000 patient exposure records in our system in hopes of answering, or at least providing evidence to support an answer to, questions previously unaddressed. As examples, I have included Figures 8, 9, and 10. In Figure 8 we asked, how does the age of the x-ray equipment affect the exposure distribution? Of particular interest in this Figure is the exposure distribution of certified dental systems versus systems manufactured in the years 1965 through 1974, which are not certified. In Figure 9 we looked at exposure distributions for different dental x-ray equipment manufacturers. It is obvious that in terms of measured skin exposure, Brand X equipment is the highest, Brands A, B, and C are essentially tied for lowest and Brand Z somewhere in between. Figure 10 shows the comparison of exposure distributors by type of facility. Notice that, on the average, it is better to get a lumbar spine exam at a hospital than at a clinic.

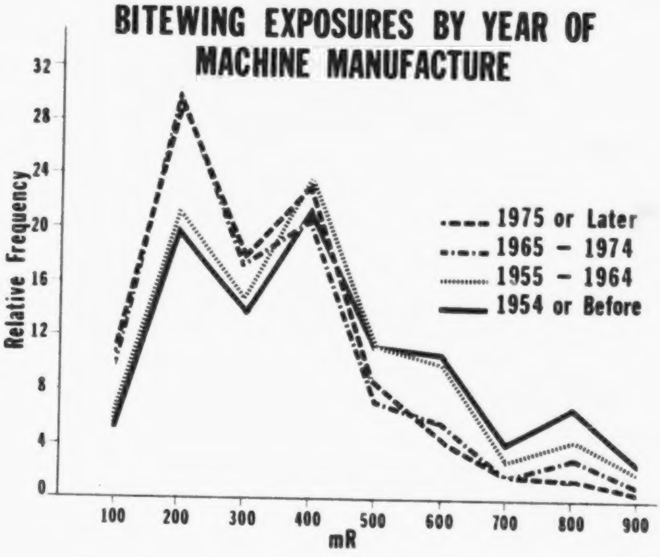


Figure 8

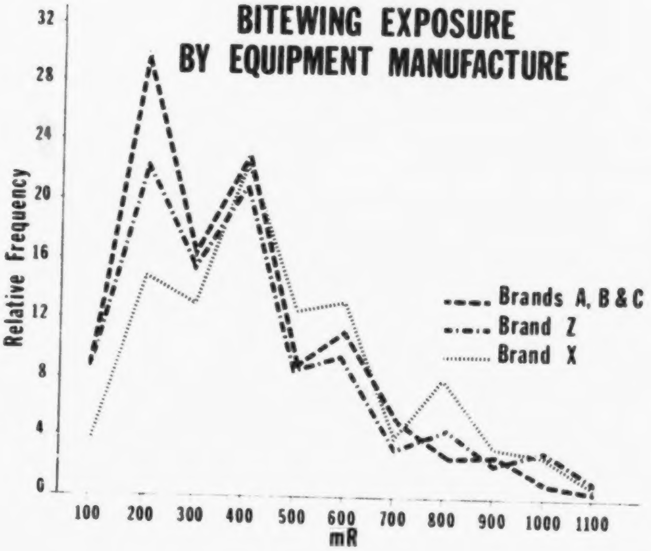


Figure 9

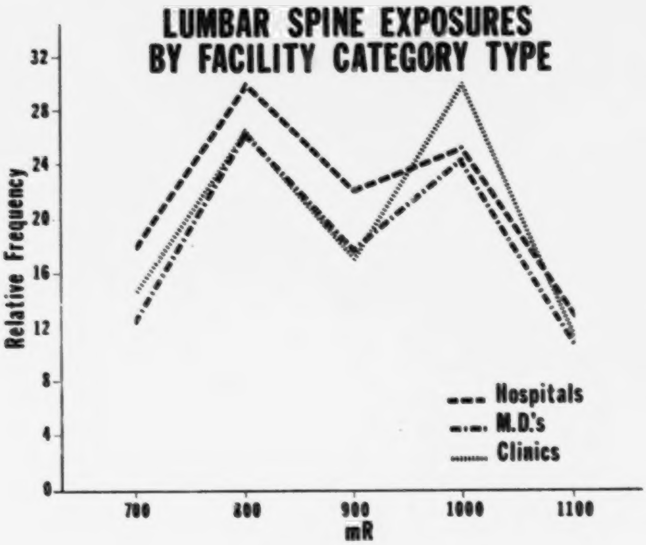


Figure 10

In conclusion, we feel we have continued progress with our exposure limit philosophy. Again we stress the importance of educating the radiation users, which is paramount in the exposure limit concept. We do not wish to imply that the concept is the "all perfect" method to reduce patient exposure but we can state that a regulatory approach of this type does seem to have a direct impact on reducing patient exposure, which is the name of the game. We anticipate continued cooperation with the dental and medical professions and a continued reduction in patient exposure.

PATIENT EXPOSURE in CHEST RADIOGRAPHY

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Division of Training and Medical Applications
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The purpose of this talk is to show an analysis of the chest exposure data that has been obtained from the Nationwide Evaluation of X-Ray Trends (NEXT) program in conjunction with Image Receptor Module (IRM) data obtained primarily through the compliance contracts with various State agencies. I will identify two major types of chest techniques and describe their relationship to the NEXT distribution of exposures and provide a cautionary note on the uses of the 30-mR entrance skin exposure guide in Recommendation Number 10 of the Presidential Directive.

From the X-Ray Exposure Studies (XES) data in 1964 and 1970, we know that the chest examination is the most frequent medical exam performed in the United States. This exam accounted for 46 percent of all medical radiographic exams performed in 1970. Table 1 indicates that 76 million persons had medical radiographs taken in 1970 and 48 million had chest radiographs.

Table 1. Estimated annual medical x rays by numbers of persons exposed and numbers of chest examinations

PERSONS EXPOSED*	NUMBER IN MILLIONS
MEDICAL RADIOGRAPIC	76
CHEST RADIOGRAPHIC	48

CHEST EXAMINATIONS	NUMBER IN MILLIONS
RADIOGRAPHIC	49
PHOTOFLUOROGRAPHIC	10

*INCLUDES 9.7 MILLION PERSONS HAVING PHOTOFLUOROGRAPHIC EXAMINATIONS.

(XES 1970)

Table 2 shows the age distribution of the people who had chest exams and indicates a general increase with age. Among individuals 45 and over, the exam rate is nearly 50 exams per 100 persons.

The most recent information on patient exposures is, of course, the data collected under the NEXT system. NEXT data collection began in 1972 with a few participating States. There are 42 States, Department of Defense , and other Federal agencies submitting data to the system. Data from the first 5 years of NEXT, 1973 through 1977, contains information on 6,631 chest P/A projections. The P/A chest projection is more frequently surveyed than any other NEXT projection.

Table 2. Estimated annual distribution and rate of chest x-ray examinations by age (includes photofluorographic)

AGE	PERCENT OF CHEST EXAMS	RATE PER 100 PERSONS
UNDER 15	9	9
15-29	22	27
30-44	22	39
45-64	32	46
65 AND OVER	15	46

(XES 1970)

The basic NEXT survey, as you know, does not include information on the image receptors used in the exam. An Image Receptor Module (IRM) was developed as an add-on to the NEXT system in 1976. This module provides additional information on type of film and screen used, whether or not a grid was used, some processor information, and so on. To date, 620 NEXT chest projections have associated IRM data (about 10 percent of the total inventory of chest projections).

The NEXT exposure data collected over the period 1973 to 1977 ranged from under 5 mR to over 100 mR for a single chest P/A projection (Fig. 1). The variation of technique factors, image receptor systems, processing conditions, and grid use contribute to this wide range of entrance skin exposure (ESE). The average value is 21 mR, the median is 16 mR, and the third quartile is about 30 mR. The difference between the mean (21 mR) and median (16 mR) reflects the shape of the exposure distribution, the tail of high exposures having more effect on the mean than on the median.

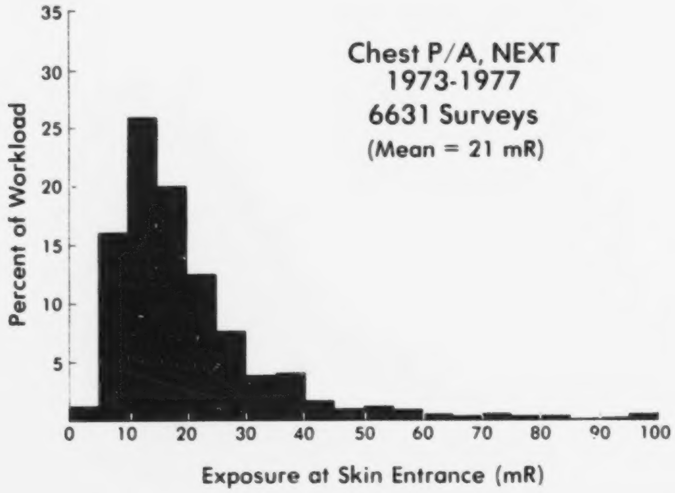

Figure 1. Frequency distribution of chest exposures.

The average NEXT values have not changed much since 1973 (Fig. 2). XES 1970 showed, by comparison, an average ESE for P/A chest of 25 mR. Table 3 shows that the chest P/A produces quite small doses to body organs. As a reminder, the lateral chest exposure generally requires about three times the exposure of the P/A projection.

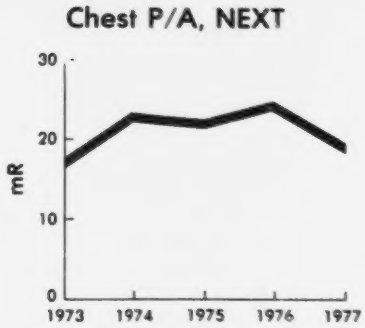

Figure 2. Mean exposure at skin entrance by survey year.

Table 3. Mean organ doses for radiographic P/A chest projections.

BODY ORGAN	CALCULATED DOSE (MRAD)
OVARIES	< 0.5
TESTICLES	< 0.5
RED BONE MARROW	1.9
THYROID	0.5

(NEXT 1973-1977)

Still, there are a large number of chest projections being made every year. While this is not the most significant exam in terms of population exposure, it is one of the most important by the sheer numbers involved.

I would like to turn now to the techniques used in chest radiography. The source-to-film distance (SFD), x-ray tube potential (kVp), half-value layer (HVL), and use of grid are technique factors of interest in analyzing chest radiography. NEXT indicates that about 95 percent of chest radiographs are performed at 72 inches. Of over 6,600 surveys, only 9 recorded a 120-inch (10-ft) SFD.

Table 4 shows that in the 620 IRM surveys, chest films were manually processed in 28 percent of the cases (only 3 percent of the hospital and 62 percent of the private offices surveyed use manual processing). Caution: remember IRM data collected with compliance contracts--mostly new equipment. Grids were used in 28 percent of the IRM surveys (Table 5).

Table 4. Distribution of P/A chest film processing by type of facility.

TYPE OF FILM PROCESSING	ALL FACILITIES	HOSPITALS	PRIVATE PRACTICE	OTHERS
AUTOMATIC	72%	97%	38%	83%
MANUAL	28%	3%	62%	17%

(IRM 1976-1979)

Table 5. Distribution of P/A chest projections by grid use.

GRID USED	PERCENT OF SURVEYS
YES	28
NO	72

(IRM 1976-1979)

The kVp used during a P/A chest projection is another technique factor of interest. Figure 3 shows the frequency distribution of NEXT chest data by tube potential. The majority of cases fall between 70 and 85 kVp, with a few cases in the 100-120 kVp categories. By breaking out the kVp data by grid use (Fig. 4), we see that, as expected, more of the techniques above 100 kVp use a grid. (Note that each of these histograms is plotted as a percentage of the number of surveys in its respective category, and that the actual number of surveys with grid is considerably less than the number without grid.)

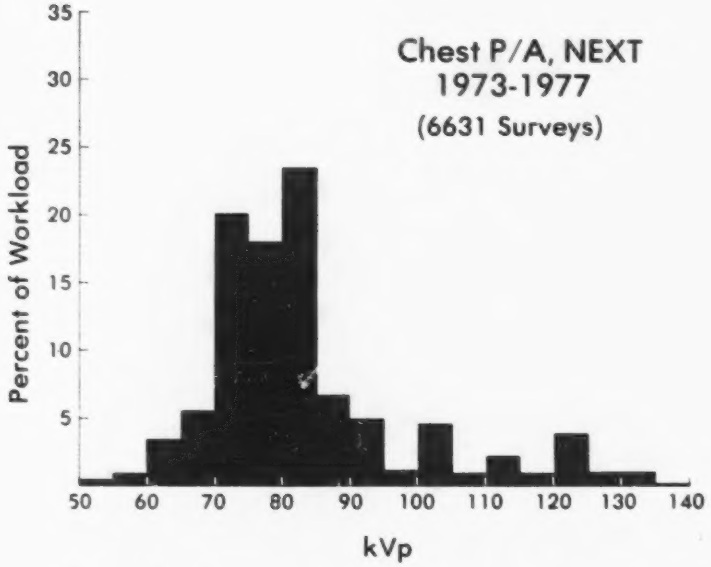

Figure 3. Frequency distribution of indicated x-ray tube potential.

While NEXT did not collect data on techniques using automatic exposure control, the 1970 XES study did. Figure 5 shows the kVp associated with automatic and manual machine timing. Note that automatic exposure control units accounted for 10 percent of the total chest films in 1970. I would expect that this percentage has grown significantly by 1979. It seems here that facilities using automatic exposure control tended to use higher kVp than those with manual units.

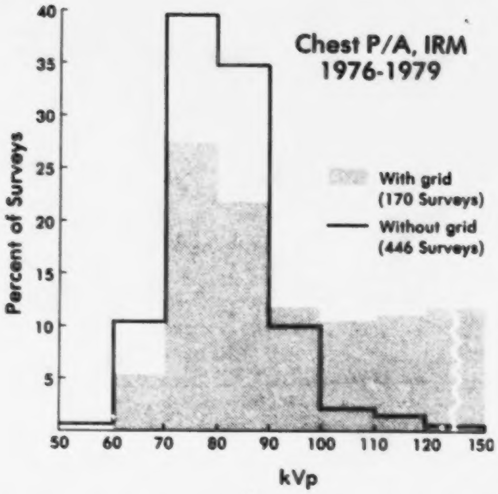

Figure 4. Frequency distribution of indicated x-ray tube potential for grid and nongrid techniques.

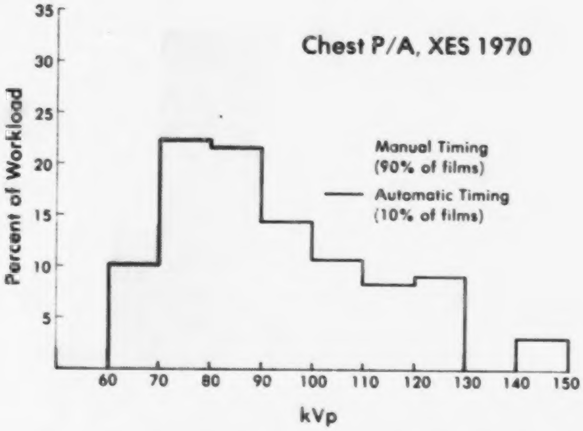

Figure 5. Frequency distribution of indicated x-ray tube potential for manual and automatic exposure control units.

Currently the Bureau is conducting a special survey of automatic exposure control units. Figure 6 shows a clear predominance of high kVp's and results from a survey of 72 units. Also it should be noted that grids were used in 85 percent of these cases, further pointing to the tendency to use grids with high kVp techniques. These data, by the way, indicate one of the shortcomings of the NEXT system, which can evaluate only manually-timed projections. These data were obtained in conjunction with compliance contracts and this might bias the conclusions because of the new x-ray machines included. However, it shows that chest data taken only from manually-timed x-ray machines may not accurately represent the practice of chest radiography in the United States. Data are needed both on relative use of automatic exposure controlled units for chest exams and on the resulting patient exposure.

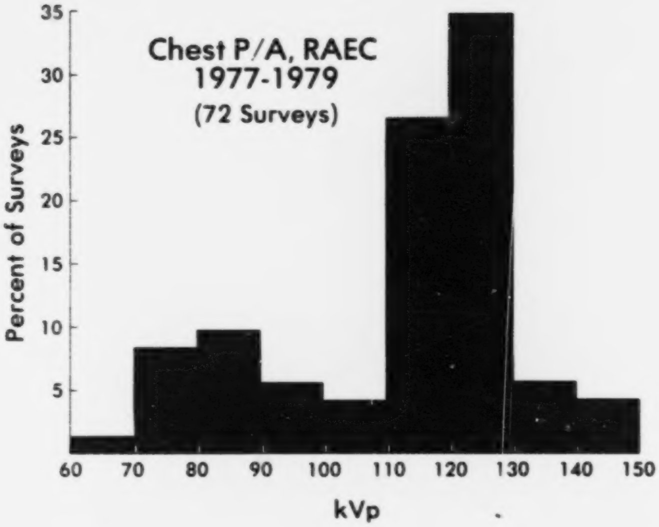

Figure 6. Frequency distribution of indicated x-ray tube potential for radiographic automatic exposure control units.

Relative speed values have been assigned to many of the film/screen combinations reported in the IRM surveys. Traditionally, the indices indicate speeds relative to the combination of Kodak RP film and duPont Par-Speed screens, which is usually assigned a relative speed index of 100. Combinations with twice the speed as an RP/Par combination would require 1/2 the exposure and would have a relative speed of 200. In the 620 IRM surveys, 125 different film/screen combinations were used for chest projections and the speed index values ranged from 53 to 305. The slowest system corresponded to someone using Kodak X-omatic G film used with Kodak regular screens for a chest examination, the fastest system was Kodak RP film in combination with duPont Quanta II screens (a rare earth system) (only 1 survey).

Figure 7 shows the distribution of film/screen speeds. Nearly 1/2 of the image receptor speeds fall in the 100 to 125 range. This would be representative of systems such as Kodak RP/duPont Par, or Hi-Speed Screens. Comparable speed films would include Kodak Blue Brand or Cronex 4 by duPont. About 20 percent of the film/screen combinations fall in the 150 to 175 speed range. This would include such combinations as duPont Cronex 4 or Kodak RP film with duPont HiPlus screens.

While there are probably several categories of techniques for chest exams, it would be instructive, I think, to look at the exposures from two typical classes of techniques used in performing PA chest exams. As we saw from the kVp data, there is a predominance of surveys that fall between about 780 kVp to about 85 kVp and then a rather long tail to the distribution which starts somewhere around 100 kVp. In general then, it seems that two techniques could be identified as those exams performed at about 80 kVp and those at about 120 kVp. While the NEXT data does not demonstrate that high kVp distribution very well, remember that photo-timed units, when included in the NEXT survey, must use manual techniques in order to be surveyed. I think it is helpful to go back to Figure 6 and look at the kVp distribution for photo-timed units in our special survey. Here it is pretty clear that there is a peak around 120 kVp. If we assume then that the same kind of distribution would occur in the NEXT data if automatic exposure controlled units were evaluated under normal use conditions, then we can define some limits of the techniques and use the NEXT and IRM data to look more closely at these two selected techniques.

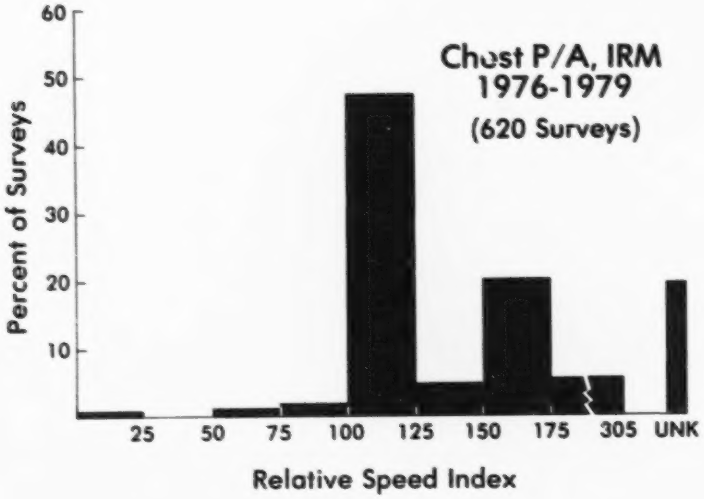

Figure 7. Frequency distribution of relative speed index of image receptor system.

We defined the two techniques as: low kVp (70 to 85 kVp)--no grid and high kVp (95 to 120 kVp)--with grid. We found the average for the two sets of techniques and looked at the image receptors used. The result was the following: low kVp--no grid technique results in a mean exposure of 22 mR and a median of 16 mR, a distribution very similar to the complete data on chests. The high kVp-grid technique for PA chest exams results in a mean exposure of 33 mR and a median of 30 mR. The image receptor speeds for both cases is equivalent, suggesting no real difference in the way image receptors are chosen for these two kinds of techniques.

This leads me to the cautionary note I suggested in my opening remarks. Using NEXT data as is, without qualification and without analysis, to develop guides or regulations which might restrict one technique in favor of another simply on the basis of entrance skin exposure (ESE) might be unfair, or worse yet, detrimental to the health care system. A conference was held last week in Madison, Wisconsin, to discuss the techniques used in chest radiography. It seems that if a consensus could be drawn from the discussions last week for the routine primary chest exam, where no specific pathology was suspected, the technique recommended was 120 kVp with grid. This was suggested as appropriate in order to partially penetrate the mediastinum and the heart without overexposing the lung field.

Right now, I cannot see how we can recommend one technique over another without a lot more information about how physicians perform in detecting and diagnosing abnormalities demonstrated by the two kinds of techniques. It would be obvious to any of us, with some close observation, that the two techniques produce different kinds of films but I, at least, am not ready to recommend one over the other. The situation here is much like the situation we found in mammography if not even more complicated; different kinds of techniques produce different kinds of images and the best we can hope to do is to try to optimize the techniques that are used.

In chest radiography, I think we have quite a lot of work ahead to analyze the various systems before we can provide guidelines similar to those we developed for mammography. We are beginning to work on this problem, but with the large number of variables involved in the techniques, it will take time to organize this and understand it.

IT'S TIME to TALK about RED (RADIATION EXPERIENCE DATA)

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Director, Division of Training and Medical Applications
Bureau of Radiological Health, FDA

The Bureau of Radiological Health, in conjunction with State radiation control programs, has collected data on exposures to medical x rays through the Nationwide Evaluation of X-Ray Trends (NEXT) program since 1972. The Bureau also has programs in mammography, Breast Exposure: Nationwide Trends (BENT) and dental radiology, Dental Exposure Normalization Technique (DENT), which determine patient exposure as well as evaluate and improve radiographic quality. However, none of these programs obtain comprehensive data on the characteristics or number of persons getting the many types of medical x-ray examinations.

In 1964 and again in 1970, the Public Health Service carried out extensive X-Ray Exposure Studies (XES-64, XES-70) of the United States population to determine exposure as well as gonad and genetically significant doses.

Following consideration of the feasibility of repeating the 1970 XES, the Bureau decided to try another approach to obtaining Radiation Experience Data. This project (given the acronym RED) would attempt to gather data directly from the diagnostic facilities, taking advantage of the growing use of computers in the medical area. The RED project was planned to collect data on all diagnostic radiation modalities including medical x rays, in vivo nuclear medicine, and ultrasound procedures.

The data collected would include only the age and sex of the patient, and the date and type of examination. A patient identification would be included initially for error checks but would not be retained on the record files. While these data are less detailed than that gathered by the XES studies, it is hoped that this minimal data could easily be supplied by medical facilities. Those facilities that have the data on computer would be asked to supply computer tapes of the information. Those that do not use a computer system would be asked to supply us with copies of their radiology log sheets. Transfer of the data into computer format for analysis would be done by the Bureau. This type of study should cost considerably less than the previous X-Ray Exposure type study, which involved an extensive survey of the population of the United States.

The first phase of the RED project will include only hospitals. A sample of 126 short-stay hospitals, stratified into five bed-size categories, has been selected. Participating hospitals will be asked to submit information on in-patient and out-patient procedures. RED would gather and generate data continuously. A system for rotating facilities, perhaps on a 3-year basis, with appropriately selected substitutes, is being developed.

Currently, nonhospital facilities such as clinics, private medical offices, dental offices, and so forth, are not included. If the hospital phase of RED proves feasible, expansion of the project to collect data from these other facility types will be considered.

Prior to contacting the hospitals, the concept of this project was discussed with members of the American Hospital Association, the American College of Radiology, the Society of Nuclear Medicine, and the American Institute of Ultrasound in Medicine. These professional organizations reviewed our plans and have endorsed the RED project and encouraged their membership to participate if requested.

Formal invitations to participate in RED were sent to the sample hospitals on February 16, 1979. The goal is to start data collection on or about January 1, 1979.

RED data on characteristics and numbers of diagnostic examinations can be used in conjunction with exposure evaluation programs such as NEXT to determine trends in diagnostic radiology. As shown in Figure 1, RED will allow us to determine problem areas and suggest which areas would be amenable to corrective action programs. It will also, in turn, serve as evaluation mechanism for action programs designed to reduce certain types of examinations. While the RED data will not be detailed enough to identify all potential problems, they can be used to indicate areas in which more detailed studies need to be done, and may be able to identify types of facilities where such detailed studies may have the most chance of being successful.

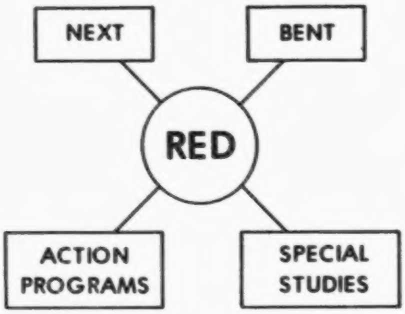

Figure 1. Interrelation of RED to other BRH programs.

Basic RED data will update much of the information last obtained by XES in 1970. The total number of various types of examinations performed in hospitals each year will be extrapolated from the RED survey data. The data will reveal trends in examinations over time as well as changing proportions of examinations in x ray, nuclear medicine, and ultrasound. Age and sex data will allow identification of changes in examinations by these characteristics.

The RED system was designed to allow projections of nationwide data. The sample was selected such that data can be provided for the four census regions of the country. Trends among these individual regions could be assessed periodically; however, the number of hospitals is too small to allow analysis or projection of data to the State level.

NARM OVERVIEW

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If x rays are the stepchilden of the radiation regulatory system, then surely naturally occurring and accelerator-produced radioactive materials (NARM) are the poor relatives.

Even though such early researchers as Henri Antoine Becquerel and Pierre and Marie Curie (1,2) each personally experienced the deleterious effects of radiation from naturally occurring radioactive materials, there was no World Food and Drug Administration or World Environmental Protection Agency to rush to ban these noxious carcinogenic materials from the earth's commerce and use. Society is probably lucky they did not get banned since there is a body of opinion, albeit a minority view, that says some good has come from radioactive materials.

Nevertheless, by the 1920's, there had been enough manifest injuries from naturally occurring radioactive materials and x rays to gain the attention of users and to foster the development of protection standards. These early standards, which were developed by nongovernmental groups, were mere recommendations or suggestions. In 1934, in its second handbook addressing radiation protection, the National Bureau of Standards (NBS) published the recommendations of the Advisory Committee on X-Ray and Radium regarding safety practices that should be observed when handling and transporting radium in quantities up to 300 milligrams (3). This was the first in a series of NBS handbooks addressing radioactive materials; my personal favorite in the series is NBS Handbook 38 entitled Protection of Radium During Air Raids (4) which was published in 1942. These early NBS handbooks were as a matter of reality limited to one naturally occurring radioactive element, radium.

World War II, the Manhatten Project, the Atomic or Nuclear Age, and the myriad, exotic new radionuclides that resulted thrust themselves upon us and pushed the naturally occurring radioactive materials into the background. A whole new Federal agency, the U.S. Atomic Energy Commission (USAEC), was established to regulate (and promote) the use of these new radioactive materials which were grouped under the strange-sounding names of "byproduct, source, and special nuclear materials." Those queer radionuclides produced with accelerators just seemed to have been lost in the rush. The U.S. Congress (in its infinite wisdom) apparently never got the message that radiation from NARM could be just as harmful as that from the materials placed under the regulatory control of the USAEC, or perhaps it felt they were insignificant.

In the late 1940's and the 1950's some States began to promulgate radiation protection regulations which addressed x rays and those radioactive materials not under USAEC control; i.e., NARM. For example, the first regulations dealing with sources of radiation in Texas were promulgated in 1956 (5).

The U.S. Public Health Service and the Bureau of Radiological Health (BRH) took NARM under their wing and tried to assist the States in their individual, uncoordinated regulation of NARM. Courses in radium hazards and control were presented for State employees. From about 1964 to 1969, the Radium Incident Report was published periodically. The BRH published numerous reports on NARM, and particularly radium, including the classic report entitled A Collection of Radium Leak Test Articles (6). The first real attempt to get some sort of identification of suppliers and a uniform evaluation of NARM products appears to be a short paper prepared by James S. Benson and published in January 1966 entitled "Interim Directory of Companies Handling Radium and Radium Containing Devices or

Compounds" (7). About 1970, the BRH instituted the Radioactive Material Reference Manual (RMRM) (8) as a NARM complement to the USAEC's Sealed Source and Device Catalogue (9); the RMRM provided the mechanism for the voluntary dissemination of NARM product identifications and evaluations by the States and the BRH.

Paralleling this dissemination of technical information and training and NARM product information was the development of model State legislation and regulations addressing all sources of radiation including NARM. Although the first edition (and all subsequent editions) of the Suggested State Regulations for Control of Radiation (SSRCR) (10) published in September 1962 called for the licensing of the posssession and use of NARM, today only 30 States license NARM.

With the SSRCR and the RMRM in place, it would appear that the uniform regulation of NARM would have rapidly followed; however, it did not. The great weakness in the system was that no one or agency had a hammer to hang over the head of the nonconforming State similar to that the USAEC held over the Agreement States. The system depended entirely upon the "voluntary" participation and implementation by each of the States at its own volition or by the gentle persuasion of the BRH.

The formation of the Conference of Radiation Control Program Directors (CRCPD) presented the vehicle for the next step toward a uniform identification and evaluation of NARM products. At the Seventh Annual National Conference on Radiation Control in 1975, a CRCPD workshop studied the problems associated with NARM products and recommended that a task force be established to "... formulate a uniform control program for 'NARM' regulation ..." (11). As a result, the Executive Board of the CRCPD established Task Force No. 1: Evaluation and Distribution of Radioactive Sources and Devices Not Manufactured Under the Atomic Energy Act (commonly called the NARM Task Force).

In July 1977, the Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) (12) was published and distributed. These "NARM Guides" outlined the procedures to be followed and criteria to be met by all NARM products authorized to be distributed by the current edition of the SSRCR. The two most commonly heard excuses for not having previously evaluated NARM products were alleviated by the NARM Guides. The excuse that there were no uniform procedures, standards, and criteria with which to evaluate a product was null because the NARM Guides presented detailed guidance. Likewise, the excuse that a State program did not have enough staff, time, equipment, and so forth to evaluate a NARM product became a moot point because of the variety of options for joint State and BRH evaluation that were presented.

The members of Task Force No. 1 were therefore surprised, and quite frankly disappointed, when they met in July 1978 and reviewed the RMRM. They found 86 RMRM Product Identification Sheets (several with more than one product identified) for which no evaluation had ever been performed. As a result of this review, Task Force No. 1 prepared letters for the Chairman of the CRCPD to send to the radiation control program directors in 12 States requesting they evaluate these products. At a meeting of Task Force No. 1 in February 1979, the status of these requests was reviewed, and it was determined that only two of the States had completed the evaluations requested. As a result, the Chairman of Task Force No. 1 sent a followup letter to the ten offending States. The response to this letter has been encouraging.

That brings the NARM control saga up to the present. What does the future hold? Items currently being worked on by Task Force No. 1 include:

1. Publishing of a revised, or second edition, of the NARM Guides, which will include an amendment of NARM Guide 2 addressing extended leak test intervals for sealed sources and two new NARM Guides:

   a. NARM Guide 13: Standard NARM Licensing Conditions.

   b. NARM Guide 14: On-Site Surveys of Manufacturers, Assemblers, or Distributors of NARM Products.

2. Getting all NARM products identified in the RMRM evaluated by the responsible State.

3. Developing and publishing of additional NARM Guides regarding:

   a. CONDOS methodology for evaluating the radiation dose to the general public for consumer products containing NARM.

   b. Interaction and coordination between the States, the BRH, and the Bureau of Medical Devices in connection with the evaluation of medical devices containing NARM.

Later today and tomorrow there will be additional presentations on these and other regulatory aspects of NARM. Task Force No. 1 would appreciate any comments on or suggestions for improving the uniformity and quality of the NARM regulatory process.

In view of the Federal Government's failure to provide a regulatory program for the possession, use, and distribution of NARM products, it is essential that the States develop an adequate, comprehensive, and uniform system for the regulation of NARM products. The system delineated in the NARM Guides provides the mechanism and has great potential. However, it is up to each State to ensure that the system works by unselfishly devoting its time, people, and other resources to this voluntary NARM control program.

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DISCUSSION

MR. GALPIN: I would like to hear reflections from several members of the Board or any State representatives here. I gathered that you were chiding the "Feds" that they should have stepped in and made some regulatory action relative to these natural radioactive materials and yet I hear a lot of State people say that the "Feds" are doing too much already and should leave some things to the States. This is an area that has always been run by the States and there is no real basis for Federal authorities stepping in and taking over except if one wants to acknowledge that the States cannot do it. But within the typical health laws of this Nation, this would typically lie within the purview of the States. I hear States on both sides --and I do not know how to get my own sense of where the States stand on this.

MR. BAILEY: I think the problem basically is that because there is no Federal regulation of these materials, it is very difficult to control imports and it is very difficult to control interstate sales and distribution. You are correct in that the States do not want you to take over something they are already doing. However, there are a few of us who would like someone to take over where the States are not doing anything. As I mentioned, the suggested regulations since 1962, the very first edition, have called for the licensing of NARM. And I realize there are problems in getting laws enacted in States and getting them accepted through lethargic health departments. But still it seems to me that all of the 25 Agreement States license NARM although there are only 5 other States of the remaining 25 States that license NARM today. The States are not going to do it, and I think it is a big enough problem that the Federal Government ought to. The Conference essentially said, yes we would like some Federal agency to regulate it, but we would like for the Federal agency that takes it over to recognize not only the Agreement States but the licensing States--States that already have licensing programs should be recognized and not preempted summarily.

NORM OVERVIEW

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Louisiana State Department of Natural Resources

As it was just brought out, naturally occurring radionuclides are omnipresent in the environment. Under various circumstances these radionuclides, mainly those from the uranium and thorium decay chains, can contaminate the environment to the extent that a real or potential risk to public health may exist. Such occurrences are well-founded in case of wastes and byproducts of the uranium industry and, quite appropriately, concerted Federal and State efforts have been devoted to resolution of the problem and in preventing a recurrence. This is also true in certain aspects of the phosphate industry, mainly those that involve dwellings constructed over reclaimed mining land. Overall, however, the investigation and regulatory control of the impacts of most of these sources have been largely overlooked by both Federal and State agencies.

Back in 1974, during the Annual Conference in San Antonio, a workshop was held to examine what standards were needed to control radioactive materials in the non-nuclear industries. Based in part on recommendations of that workshop, the Conference, in the following year, established a task force to assess contamination by naturally occurring radionuclides and assist the States and Federal agencies in developing appropriate radiation protection guidance and criteria.

I should like to use this opportunity to highlight the recent activities of Task Force No. 7 on NORM and discuss a possible approach to initiating State control over these materials.

NORM is the acronym for Naturally Occurring Radioactive Material as opposed to NARM which was just described by Ed Bailey. To distinguish the intent and scope of responsibilities between Task Force No. 1 - Natural and Accelerator Produced Radioactive Materials and Task Force No. 7 - Natural Radioactivity Contamination Problems, the following clarification was proposed to avoid confusion:

a. Task Force No. 1 will cover products containing natural or accelerator-produced radioactive materials introduced deliberately for their radioactivity and/or physical/chemical properties.

b. Task Force No. 7 will direct its efforts toward naturally occurring radioactivity present in products, byproducts, wastes, and effluents, not introduced deliberately for its radioactive and/or physical/chemical properties.

So we on Task Force No. 7 are concerned with what has become known as "technologically enhanced natural radiation" or exposures to truly natural sources of radiation that would not occur without, or would be increased by some technological activity not expressly designed to produce radiation.

In our technological society there are many routes of human exposure to NORM and the scope of the exposures and accompanying problems in the United States is obviously very broad. Most, if not all of the States and the Federal radiation regulatory agencies have made concerted efforts to control and reduce radiation from x-ray machines, radiopharmaceuticals, and nuclear power plants. Conversely, the control over NORM radiation, which in some cases can be more significant than any of the radiation sources mentioned above, has been extremely limited. I feel that now is the time for two general questions to be seriously considered by State and Federal regulatory agencies. The first is, What are the population dose increments from NORM sources and how do these doses and risks compare with other radiation sources? The second question--Are radiation controls on NORM sources needed, and are such controls feasible? Once these concepts have been given consideration, more specific problems must be addressed, such as:

a. Should phosphate slag be used for street and road construction or for other purposes?

b. Should phosphate gypsum be used as a soil conditioner, and if so, would any restrictions on such use be appropriate?

c. Should the production or distribution practices of radioactive fertilizers be prohibited, modified or limited in any way?

d. Should foundries and phosphate plants be licensed, and what restrictions should be imposed on disposal of solid wastes containing NORM generated by these industries?

e. Should monazite or zircon sand be used and distributed in commercial products such as tape dispensers?

f. Should zirconium extraction sludge be distributed on agricultural land as a soil additive?

g. Should coal fly ash be used in construction materials?

Undoubtedly there are more significant questions regarding dose pathways, but presently not enough is known about these pathways or the radiation levels to ask the pertinent questions. The answers to such questions would reasonably depend on the population dose increments (person-rem) involved, the risks from the dose increments (ill-health effects), the benefits of accepting the risks (dollars and other factors), and the cost of eliminating or lowering the risks. Assuming all these factors could be quantified, the task now becomes one of defining an "undue radiation risk from NORM" and thus establishing the criteria of acceptibility.

Currently since all State regulations prohibit the use of radioactive materials unless authorized by a license or exempted, and since most NORM is not exempted, all NORM should be licensed, regardless of concentration or quantity. This would not be satisfactory. The approach that the Task Force will be recommending down the road is to include an exemption for NORM licensing or controls in the State regulations. Ultimately the exemption could read something as follows:

> Sec. C.4 RADIOACTIVE MATERIAL OTHER THAN SOURCE MATERIAL
>
> (g) Exempt Quantities or Concentrations of NORM
>
> Any person is exempt from this part to the extent that such person uses or disposes of quantities or concentrations of NORM contained in industrial products, industrial byproducts or commercial products, provided that the use or disposal of such quantities or concentrations of NORM does not result in an undue radiation risk to the public health and safety, as defined in Part A of these regulations.

It would be necessary, upon adoption of the above exemption, to remove radium from Schedule A, Part C, of the Suggested State Regulations if this has not been done previously. The present values of 0.1 pCi/g for Ra-226 and 0.3 pCi/g for Ra-228 in Schedule A are not reasonable, since many common rocks and other materials contain concentrations above these values.

We are currently attempting as a task force to initiate the process that will eventually lead to a reasonable mechanism for the evaluation and/or protection of the occupational and public health from exposures to NORM sources. To summarize where we stand, 1 year ago in Harrisburg, we had available for distribution our initial task force report and you should have all received a copy. If you did not and would like to, please let one of us know. We felt at that time that this publication provided a fairly thorough compilation of information relating to sources of exposure from technologically enhanced natural radiation. However, it appears from information we are receiving, and from sources new to us that are being uncovered, that while we may have described some of the major known industries, we have merely scratched the surface of the overall problem.

Subsequent to completion of our initial report, we began developing a comprehensive NORM inventory, which lists industrial activities and domestic locations with corresponding natural radioactive products, byproducts, or wastes including isotopic concentrations, and dose-rates. This has been developed partially as a result of the State input we have received and I would like to express our appreciation to the States who have contributed their time and effort in assisting the Task Force. Accompanying the inventory will be radiation dose pathways tables that identify the routes of human exposure. They will identify the radioisotope constituent, the use or storage mode, the ultimate disposition, and the typical gross radiation or radioactivity levels. Since these tables are both fairly lengthy and time-consuming, they probably will not be completed prior to the end of this year; and we are still soliciting State input for incorporation into the tables. Right now there are a lot of blank spaces that need to be filled in. We plan to make both the inventory and the pathways available to the States and interested parties when available.

We feel there is a definite need to evaluate the radiological aspects of each of the dose pathways in order that determinations can be made regarding the relative radiation hazard involved allowing for decisions to be made concerning the need for restrictions or controls if deemed necessary. It does appear to be the responsibility of at least three Federal agencies to evaluate the radiological aspects of the dose pathways. The Task Force recommends that the NRC, EPA, and FDA begin such evaluations as soon as possible following completion of the pathways and tables.

Just briefly on our future Task Force activities, we have under development Report No. 2, which is entitled "Dose Pathways from NORM." Included in the Report is a summary of our first report with several new chapters. A few of the topics include (1) oil well production waters, (2) Bauxite processing, (3) tin smelting, (4) monazite and zircon sands in commercial products, (5) regulation of occupational exposures in non-nuclear industries, (6) radon in caves (an update), (7) update on phosphate products and byproducts, and (8) the NORM inventory and pathways.

In closing, I would reiterate that we feel it is necessary to evaluate on a case-by-case basis each use of material containing NORM and ultimately to impose the necessary controls and restrictions to insure public and occupational radiation safety. Obviously this is not something that will come about overnight, and I would urge all concerned agencies to give consideration to a reassessment of priorities, allowing for at least a portion of time to devote toward identifying and evaluating the occurrence and use of NORM in your State.

DISCUSSION

DR. PARROTT: I would personally like to compliment the Task Force on producing the document Radioactivity and the Natural Environment. It has been very valuable to us, and of course it was particularly valuable because one of the authors worked for me and gave us some insight into some problems we never knew we had.

RADIOLOGIC ASPECTS of ZIRCON SANDS

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As a preface to the discussion of the uses of naturally occurring radioctive materials (NORM) in Oregon and its consequent radiological problems, several terms should be defined. Those terms are monazite and zircon.

Monazite is defined in part as "a phosphate of the cerium metals and the principai ore of the rare earths and thorium" (from the Dictionary of Mining Minerals and Related Terms, U.S. Department of Interior, 1968). It is a moderately to strongly radioactive mineral (Ce, La, Y, Th-PO_4). Its color is yellowish, reddish-brown, yellowish-brown, and green. It occurs widely disseminated as an accessory mineral in granite igneous rocks and gneissic metamorphic rocks. Detrial sands in regions of such rocks may contain commercial quantities of monazite. It occurs in pegmatites associated with zircon, xenotine, gadolinite, samarskite, fergusonite, magnetite, apatite, calumbite, and ilmenite. Thorium-free monazite is rare.

Related to the ore monazite is the mineral zircon, zirconium orthosilicate, the chief ore of zirconium. It varies from brown to green, blue red, golden yellow, and colorless. It is generally not radioactive, sometimes weakly to moderately radioactive. It is universally present in crystalline rocks; particularly granites, schists, and gneiss. It is a common mineral in river and beach placers. Uranium and thorium-bearing varieties are pegmatites and their breakdown products. The presence of zircon in placer deposits is nearly always indicative of the presence of monazite.

Zirconium metal is extracted from zircon ore sand--first having been prepared in its elemental form in 1824, produced in relatively pure form in 1914, and into high-purity grade in 1925. The Bureau of Mines began research with zirconium in 1944 under W.J. Kroll and a method was developed and tested commercially to produce high-purity zirconium by the magnesium reduction of zirconium tetrachloride in an inert atmosphere. Much of that early work was done at the U.S. Bureau of Mines in Albany and it was only natural that the zirconium extraction industry, using the Kroll process, took root in that city in 1953, rapidly expanding production to meet the increasing need in the nuclear reactor, chemical, and other industries where its oxidation and corrosion resistance, low neutron absorption, and other properties were of significant importance.

In addition, hafnium occurs in nature with zirconium in the mineral zircon, varying widely but with an average ratio 1:50. It is a detrimental contaminant to zirconium when the end use of that metal is in the nuclear reactor industry, because of its higher neutron absorption cross section.

The establishment of the zirconium industry and its subsequent rapid growth set the stage for our belated realization that the use of ore containing naturally ccurring radioactive materials (NORM) could represent a potentially significant radiological health hazard.

An interesting tangent to this discussion--all important to industry, however--is the economics of the zirconium market. Zircon sands used in the Northwest, originating from the Australian sources, currently are priced at about \$130 per ton in bulk, delivered; whereas, the extracted zirconium metal as sponge is priced at a range of between \$9-\$15/lb., ingot--\$11.25 to \$18.75/lb., and as fabricated in sheet, strips, bars and tubing--\$18 to \$35/lb. So, it may be seen that it is an economically important industry when you consider that 7 to 8 million pounds per year of the metal is generated by the Free World's major supplier, Teledyne Wah Chang Albany in Oregon.

Teledyne Wah Chang Albany found it necessary to separate the thorium fraction of their zircon sand in an attempt to meet the technical specification of several ppm in the final nuclear grade zirconium product. Magnetic separation was proposed and authorized by license in 1974. Two percent magnetic separation of the monazite-held thorium was achieved at a rate of 3 tons/hr. By the closing of that off-site separation operation, some 450,000 pounds of monazite was extracted from the raw zircon sand and transferred to Nuclear Engineering Company, Inc. for disposal. Ten million tons of separated sand moved on to Teledyne Wah Chang Albany for processing and removal of zirconium and hafnium, and of course carrying with the ore yet a sizable magnetically unseparable fraction of NORM. By the time that our office became interested and arrived on the scene (1977) the firm had a reported estimate of 4,000 tons of chlorinator residue as waste and 10,500 tons of chlorinator-under-flow sludge in all plant lakes and pond locations and a small inventory of hafnium residue. The on-site inventory for zircon sand in storage and process was about 2,200 tons.

Radioanalysis of the zircon sand indicated an activity of about 90 pCi/gram of Ra-226 and an activity of 35 pCi/gram of Ra-226 in insoluble sulfate form found in sludge waste that had been deposited on site and distributed over a 60-acre field. Segregated chlorinator residue as unreacted sand with soluble chlorides was measured to be a total activity of about 500 pCi/gram.

The major concern was of the potential for contamination of the ground water at and near the plant site, the Willamette River, which passes less than a mile from the plant boundary, and the well water sources near the field upon which residue was spread for soil beneficiating purposes. Radon levels over a portion of these areas exceeded the 0.03 WL--by a factor of 10 (3×10^{-6} μ Ci/cm^2/hr).

A radioactive materials license was finally issued to Teledyne Wah Chang Albany for the possession, use, and storage of zircon sands and disposal of other residue only at a licensed disposal site. That license was issued on March 28, 1978, and was conditioned upon the release limit of 90 pCi/l of Ra-226 to a local stream, scheduling of their currently held residue waste by September 1978, process waste produced after July 1 to be containerized and held in storage for periods of no longer than 60 days prior to transfer for disposal. The licensee was further held to an extensive ongoing health physics program.

At the time of the completion of chlorinator residue pile removal in August, 1978, nearly 127,000 cubic feet of material weighing 5,126 tons, with a roughly estimated total activity of 5,916 millicuries was transferred in bulk form to the Nuclear Engineering Company, Hanford, Wash., for disposal.

At this time, it can be said that our agency has obtained cooperation from the licensee --an adequate health physics program has been established, disposal schedules have been met, and process changes to reduce the volume of radium in the waste streams are being developed.

Although it was understood that zircon sand was a commonly used constituent in molds used for the casting of steel in foundries, the extent to which it was used was not fully realized. An investigation into its use in industry was initiated following an off-hand remark made by an industrial radiographer during a license inspection. The magnitude of the use of this type of sand quickly became evident when it was found that there were as many as 50 foundries in the State that were possible users. The search then began for the current users in the foundry and related industries. It was then determined that 26 industrial plants and 1 industrial supplier possessed and used zircon sand to some degree. It was determined also that those manufacturers of products such as grey iron, brass, bronze, copper, and aluminum casting, as well as cement manufacturers were not users of NORM bearing ore. Through on-site review of the 26 possible users, only 19 were found to be in possession of or using zircon sand or rare earth containing NORM in the form of sand, flour, slurry, or paint. All but five of those visited used such material as a component in the steel casting mold-making process. The remaining five used the zircon sand as either a refractory, abrasive, or, in the case of rare earth (cerium), as an additive in the glass industry.

In the making of casting molds, consideration must be given to the characteristics of the particular sand to be used relative to the type of casting to be made. The sand must be of sufficient porosity to provide escape of gas and steam formed within the mold; must have cohesive properties sufficient to provide strength in conjunction with its additives; must have a grain size appropriate to the surface to be produced; and must have a grain shape irregular in nature so as to provide prope. bonding strength. Zircon sand, as well as chromite to a lesser degree, has these qualities necessary in the carbon steel casting process as well as the required high thermal conductivity and resistance to metal penetration.

Zircon sand, mainly in slurry form, is also used in the precision or investment casting operation, a modern innovation of the ancient lost wax process, where smoothness and high dimensional accuracy is a requirement for the production of small detailed ferrous and nonferrous alloy casting.

Early findings of this investigation indicated that the zircon sands used in Oregon originated from Australian placer mines and were stockpiled in large quantities in both bulk and bagged form. Too, it was found that this ore was essentially the same as that used by Teledyne Wah Chang Albany in the zirconium extraction process and that the total activity averaged 90 pCi/gram, dry weight, each for uranium and daughters. Measurements made of a single 40-Kg bag of zircon sand was found to exhibit radiation exposure rates of 170 μR/hr at the surface and 15 μR/hr at a distance of 3 feet above the bag. Measurements made of 40 Kg bagged sand stacked upon a pallet to a size of 4 ft x 4 ft x 4 ft gave indicated exposure rates of 300 μR/hr at the surface and 80 μR/hr at a distance of 3 feet. Further, measurements made over a 2,000-ton pile of bulk sand gave exposure rates of 200 μR/hr maximum and 170 μR/hr on the average at the surface and ranged between 110 to 120 μR/hr at a height of 3 ft from the surface.

One area of concern was thought to be a possible occupational internal exposure through inhalation during the use of zircon sand, as flour (in 200 mesh or 74 μ in size). Sand of this nature is used in the mulling or mixing of the mold formula by workers (mullers) directly handling the flour by the use of scoop or dump method. Air monitoring in a high use area within one large carbon steel casting manufacturing plant and air monitoring at the breathing zone level of five mullers at that plant showed no significant zircon flour dusting. One exception was found from a sample obtained from a muller who had hand-dumped eight 100-pound bags of flour into a chute that feeds a mulling mill.

It appears that even though the flour is very fine and dusting is evident, the material is of such a size and density as to not reach the breathing zone of a mulling operator, as respirable particles, unless the individual's position is surrounded by airborne zircon flour. The density of dry zircon sand of 100 mesh or 150 μ in size is said to be 172 lbs/ft^3 and zircon flour of 325 mesh or 30 μ in size is 114 lbs/ft^3. By comparison, dry silica sand of 50 mesh or 300 μ in size is 93.2 lbs/ft^3. Two hundred mesh flour is that size found to be commonly used. It must be noted that the mesh number does not indicate the particle size spread but only the screen size through which all particles will pass. From the limited information gathered, however, it cannot be said that an inhalation problem does not exist in this portion of the mold-making process. Further study appears to be needed and an evaluation made on an individual basis.

This investigation was followed by the requirement placed upon all users to file an application with the agency for a radioactive materials license with licensing action to be based upon the stated possession, use, and disposal methods. Based upon the criteria for licensing of 57 μR/hr in the unrestricted area; 57 μR/hr with 1/3 use factor in the restricted area; 30 pCi/l of Ra-226 in the effluent released to the unrestricted area or 0.03 WL of radon in the unrestricted area, it appeared that most applicants would be exempted from licensure. With these filings now complete, it now appears that specific licensing will be necessary for three of our major foundry users and the one zircon sand supply firm.

Through examination of the information (excluding the zirconium extraction industry) it appears that there is a monthly use rate of zircon sand, in all forms (raw sand, flour, slurry, and so forth) of 516 tons a month and an estimated annual rate of 6,540 tons in Oregon for the year 1978. The rate of use is essentially equal to the rate of disposal in all cases because there is no intentional incorporation of zircon into the end product. Further, it appears that 1,584 tons of zircon sand is exported from Oregon to users in adjacent States, by the local industrial suppler, with steel foundries as the primary recipients.

All but one applicant has indicated that over the past several years and through 1979, the inventory of zircon sand on hand, rate of use, and disposal has been and will remain fairly stable. One respondent has indicated a projected marked increase in use of the sand. Three industrial firms have indicated that disposal has been on company-owned land. All other firms have stated that commercial general waste routes are used. No respondents believed that the zircon sand used by them was recoverable as stored or disposed.

In summary, based upon the investigative findings reported in this paper, it appears that the NORM bearing ore (zircon sands and rare earths) does have an economic, environmental, and health impact upon our society. It would behoove all radiation control agencies to assess the inventory of NORM in areas under their individual jurisdictions; to evaluate the potential for current and long-term exposure to the population; and to control through licensure when appropriate the source of supply, storage, use, and disposal of that material.

DISCUSSION

DR. PARROTT: Because the regulatory limit on the release of radium-226 to the outside is 30 picocuries per liter, I wish you could clarify your statement of release to a stream of 90 picocuries per liter.

MR. WAGSTAFF: Actually the 90 picocurie per liter limit that was placed upon Albany, was at the central release point into a local stream, which was within that boundary, and it was predicated upon the fact that through dilution in the stream and the extension of a mile or more of that stream prior to entry into the probable water source, which is the river, it would be far below 30 picocuries per liter. In other words, they had difficulty initially in even reaching the 90 picocuries per liter, but they accomplished that and reduced it currently down to the release point of about 30 picocuries per liter.

DR. MILLS: Let me compliment you on the depth of the inventory study, I thought it was outstanding. You mentioned biologic level but I missed something.

MR. WAGSTAFF: That was point number three.

DR. MILLS: Was that outside?

MR. WAGSTAFF: The levels I was referring to were measured levels at the field in which the sludge was used for benefiting soil.

DR. MILLS: Do you have any environmental air concentration studies in the foundries?

MR. WAGSTAFF: We have done a study in the large plant. We have one large foundry in which they make high-carbon steel castings and they have a large inventory of zircon sand and we have done air monitoring in that plant. The monitoring was limited. We saw no activity at all.

FIELD SURVEYS of PHOSPHATE SLAG USE in SODA SPRINGS, IDAHO

Bruce H. Peterson
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Idaho Department of Health and Welfare

Soda Springs is a small community of about 3500 people in the southeastern corner of Idaho. Its main industry is the mining and milling of the vast phosphate ore deposits underlying the area. These ore bodies contain higher than normal concentrations of uranium and its decay products. Mining the phosphate ore redistributes the radionuclides into the environment where they may come in contact with man.

The thermal process mill at Soda Springs reduces the phosphate ore into elemental phosphorus and a clinker-like waste material called phosphate slag. The plant has been in production since 1954 and is currently producing about 1 million tons of slag each year. This slag contains most of the radioactive materials from the original ore. The average concentration of uranium and its decay products in the slag is about 30 pCi/gm.

Because of the scarcity of economical quantities of natural aggregate, slag has been used extensively for construction purposes. Currently the use rate about matches the production rate. Probably the most radiologically significant use from 1962 until its prohibition in 1977 was as aggregate in concrete foundations of buildings. This radiologic impact is two-fold--the direct penetrating gamma radiation exposure, and the inhalation exposure from radon gas and its decay products.

In late 1977, an EPA gamma survey truck, operated by EPA and Idaho Radiation Control Section personnel, scanned the town of Soda Springs to detect the slightly elevated gamma radiation levels coming from slag used in buildings. Of the 1082 structures in Soda Springs, 340, or 31 percent showed elevated gamma levels (1). Figure 1 is a map of Soda Springs showing the anomaly sites as dark areas. An additional 25 to 30 anomalies were detected in outlying subdivisions. The truck was unable to positively identify slag containing structures because of the added presence of slag in the streets, sidewalks, and driveways. However, the large number of anomalies indicated that a followup study would be needed.

During July and August of 1978, a two-man survey team checked 278 Soda Springs structures. One hundred and fifty-six of the buildings were determined to have been constructed using slag in the concrete. The dark areas on the second Soda Springs map (Fig. 2) indicate the slag structures. Only 200 of the surveyed structures were from the original 340 anomalies. Almost all of the structures were residences.

Observed average gamma levels within these homes ranged from 11-50 μR/hr including background. As shown in Figure 3, the distribution was fairly normal, with a mean value of about 28 μR/hr. Normal background is approximately 10 μR/hr.

Guidelines for gamma exposure limits state that no individual of the general populace should exceed 500 mrem/yr, and that the average population exposure should not exceed 170 mrem/yr (2,3). Assuming 100 percent occupancy, about 50 percent of the surveyed structures exceed 170 mrem/yr potential exposure (about 29 μR/hr) but none exceed 500 mrem/yr (about 67 μR/hr).

Recently published draft EPA guidelines for Florida houses built on reclaimed phosphate land suggest that no new house should be constructed with gamma levels more than 5 μR/hr above background, but that no remedial action is indicated based solely on gamma levels (4). However, the highest measured average gamma level reported was only 27 μrem/hr, so the Florida guidelines may not be applicable in this case.

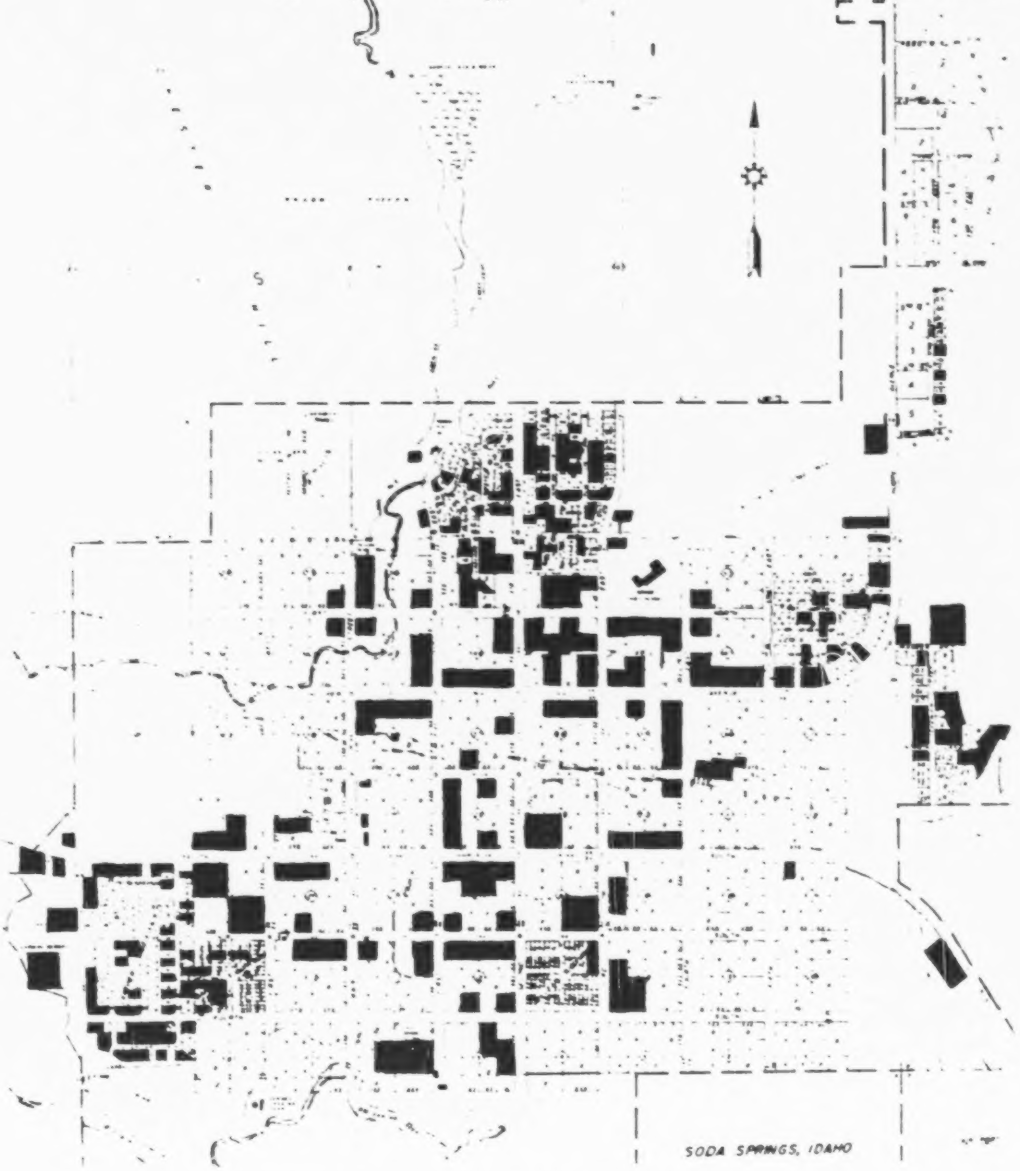
SODA SPRINGS, IDAHO

Figure 1.--RADIATION ANOMALY SITES (IN BLACK)

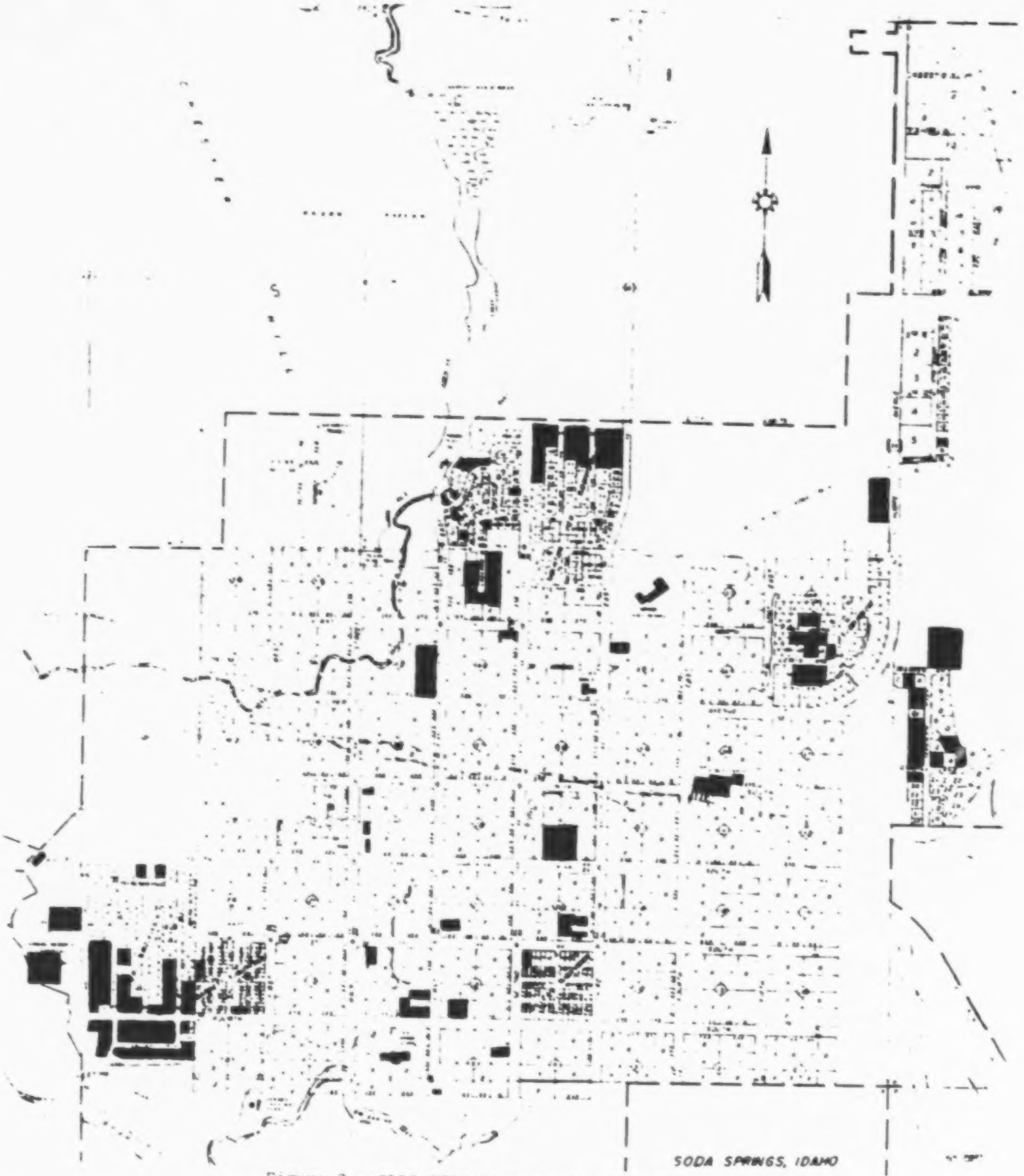
SODA SPRINGS, IDAHO

Figure 2.--SLAG STRUCTURE SITES (IN BLACK)

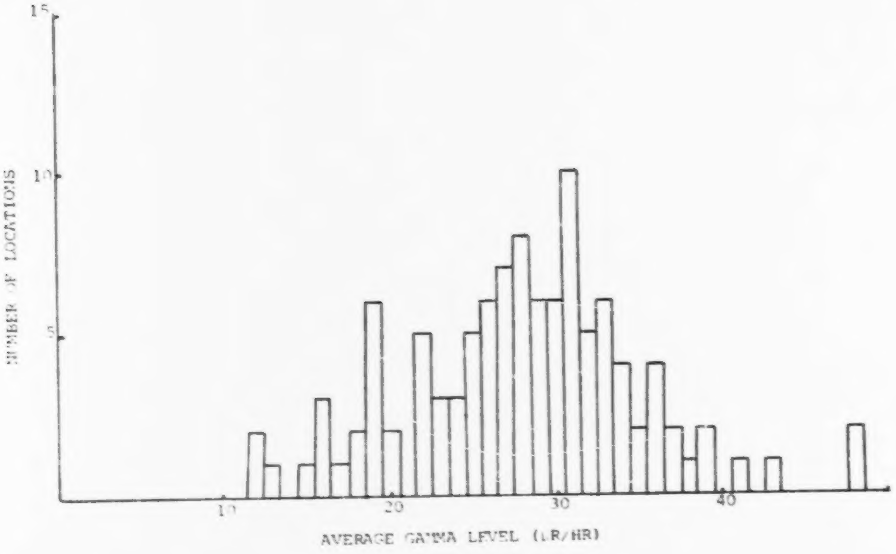

Figure 3.--AVERAGE GAMMA LEVEL DISTRIBUTION IN BUILDINGS

Radon and radon daughter grab sample measurements were made at 107 locations. The radon daughter measurements ranged from 0.0005 Working Level (WL) to 0.046 WL. A Working Level (WL) is defined as any combination of radon daughters in 1 liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha energy.) All values included background. The distribution was skewed and appeared approximately log normal. The results were plotted on logarithmic probability paper and a least squares regression line was determined, as seen in Figure 4. The median value (geometric mean) was 0.0053 WL. Normal background is about 0.005 WL.

The proposed Florida guidelines indicate that, above a gross annual average of 0.02 WL, remedial action is required and, in addition, that all practical effort should be made to reduce the levels even further. No new structure should exceed 0.005 WL above normal background.

The problem in interpreting the Soda Springs data is that the data does not fit the criteria established for the guidelines. Specifically, the guidelines are annual averages while the data are grab samples. This problem was recognized before the study began, but no solution was available given the time and manpower limitations.

The data can be looked at as individual samples from different locations. At face value, this indicates the presence of 10 locations out of 107 that exceed 0.02 WL, while 29 percent of the samples are 0.005 WL or more above background. It is well known that both radon and radon daughter levels vary greatly with such factors as barometric pressure, temperature, and ventilation rate, and that levels are normally lowest in the summer time, so this evaluation may not be representative of the true situation.

An alternative way of viewing the data is to look at the results as a class rather than as individual data points. Slag contaminated buildings have a higher concentration of radium than normal structures. Therefore, on the average, the radon and radon daughter levels in those structures should be higher than normal. While any particular structure may have low concentrations at the time of sampling because of the conditions previously mentioned, with

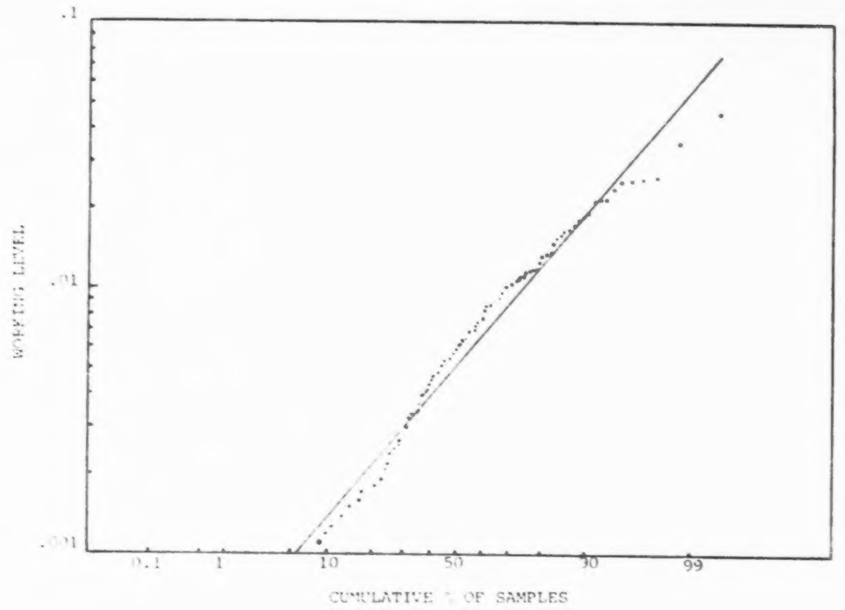

Figure 4.--LOGARITHMIC PROBABILITY PLOT OF WORKING LEVELS

sufficient samples taken over an extended period of time, the average should be valid. Working level results obtained in this study show an approximately log normal distribution with a median value that is about the same as the estimated value of normal background in this area. The log normality of background distributions has previously been demonstrated in background structures in Grand Junction, Colorado (5).

Based on this analysis there would not seem to be a buildup of radon daughters in the studied houses on the average and, therefore, no serious problem would appear to exist. Obviously, additional data is needed before a definitive evaluation can be made.

Radon measurements made at the same locations at the same time ranged from 0.05 pCi/l to 7.4 pCi/l. As can be seen from Figure 5, the radon samples were also approximately log normally distributed with a median value of 1.20 pCi/l. Background is approximately 1 pCi/l. The Idaho Radiation Control Regulations set an annual average limit to unrestricted areas of 3 pCi/l above background for radon. As with the WL samples, these values are not annual averages; however, only 7 percent of the samples appear to exceed the guidelines and the median value is again approximately background.

This study has not conclusively proven or disproven the presence of a significant health problem. It has, however, conclusively shown that the problem potential is real and extensive. Much additional data are needed to quantify the hazard. An additional 2000 anomalies have been detected in Pocatello by the EPA mobile survey truck but have not as yet been investigated.

The State of Idaho has forced the discontinuance of slag use in building construction effective June 1977, and is reviewing both this and other available data to determine if a total ban on slag use is justified. Additional investigations of both indoor and outdoor exposure levels are planned.

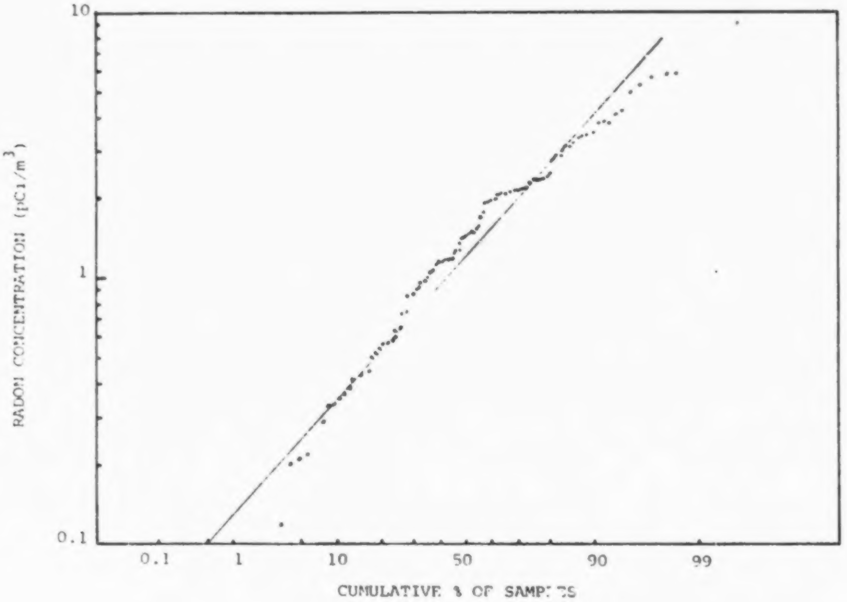

Figure 5.--LOGARITHMIC PROBABILITY PLOT OF RADON CONCENTRATION LEVELS

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DISCUSSION

MR. MONTGOMERY: Did you use a net inside gamma averaging in the homes with the same methods used in Grand Junction?

MR. PETERSON: Yes, we used the same method. The only thing we did not do was to subtract out background. All the values were gross. We took measurements on the average of about four per room on all levels and in all the rooms of the house, and did a mathematical average of those levels, but we did not subtract out background.

MR. MONTGOMERY: What were the net inside gamma averages, roughly? Is there a range or average you saw in those homes?

MR. PETERSON: The figures show the gross. All you have to do is subtract 10 from it.

DR. SOLON: Did you find any correlation between the elevated radon levels and the elevated external gamma levels?

MR. PETERSON: I plotted the average gamma levels in the structures versus the working levels in the structures and if you took a shot gun and shot at a piece of paper that is what you would see.

DR. SOLON: Essentially, no correlation.

MR. PETERSON: No correlation, whatsoever.

DR. SOLON: Do you have any feeling about why that should be?

MR. PETERSON: Yes. I think that the radon levels are determined more by the demolition rate than by the amount of slag or whatever in the buiulding. Virtually, all these buildings were basement structures with the slag in the concrete of both the basement floors and the walls, so that the gamma is fairly uniform. The emanation rate into the room therefore would be relatively uniform but the use of the building, I think, is what determines the levels of radon in the building.

DR. SOLON: Will there be whole-body counting done of the residents at all?

MR. PETERSON: No. We have no capabilities for whole-body counting.

DR. SOLON: Do you think it is warranted as part of the overall investigation?

MR. PETERSON: From my experience, I worked 5 years with the Grand Junction Program, and the New York University did whole-body counting of residents of Grand Junction and found virtually nothing in terms of elevated levels of lead-210 in the skeleton structure of the body, so I do not think it is worth it.

MR. DAVIES: Did I hear a staff directive that the U.S. FDA recommendation that...

MR. PETERSON: The average level in a slag house is about 170 millirems per year which means many levels are a lot higher than that and some are lower, as far as I can tell from reading the draft FDA guidelines which keep changing routinely and which never seem to get published. Their guidelines are going to be that normally strucures should exceed...above background, whatever background is again. However, they say that for Florida at least, no immediate action is necessary based on the gamma levels. The situation in Florida is such that--as I understand it--I have not been there so I do not know--but normally their buildings are what is called slab-on-grade construction and this slab--concrete slabs--does not normally have slag in it. It is built over land that has residues from the phosphate mining on it and therefore, the 4 inches of concrete in the slab tend to knock down the radiation levels inside the building to relatively normal levels; the gamma levels at least. In Idaho, the situation is quite different because they mine the ore well away from the town itself and then they just use the slag in the concrete because there is not natural aggregate available. They have to have natural aggregate in about 60 to 70 miles in Utah, other than slag for the concrete. So there is quite a bit of difference in the use patterns.

MR. LLOYD: I wondered if you have done any laboratory testing of the rates of radon from your phosphate slags. The reason I ask, with the Montana phosphate production we are getting our ore also from the Soda Springs area and we have tested the radon rates from the ores and also from the slag. The slag contains the same radium content as does the ore, and we are finding that the radon rate from the slag is in the neighborhood of 0.5 percent of that which is coming from the ore and we feel that there is some kind of crystalline or ceramic matrix being formed that is precluding.

MR. PETERSON: I have not done that. That is one of my proposed projects and it is also one of the reasons I think there probably is not a radon problem in the buildings in Soda Springs now. I discussed that in January back in Montana. I want to look at that.

MR. LLOYD: I have a second question and it is relevant to our Butte study. Have you tested enough nonsource forms, nonslag forms in Soda Springs to discern the difference between your nonsource forms and your slag forms?

MR. PETERSON: No. The problem we have is that we have taken grab samples in a lot of homes. We have four homes in which we have done annual averages that do not have slag in them for a working level. But we do not have sufficient long-term working level measurements to say for sure what the averages are.

MR. LLOYD: At this point, you are not certain if you can see the difference between homes having slag in them and other homes?

DR. MILLS: As to the...guideline, you are right it has been a long time. I think they are going to get them out within the next month. The wording that goes with it to make sure the interpretation is correct. But we will publish it and urge the States to take a hard look at those numbers and come back with some good critiques because I am afraid that what is going to happen is that the numbers will be picked up and used across the board and we will reach the situation in which they are not applicable. Take a hard look at it and give us some strong comments.

MR. PETERSON: I agree with you whole heartedly.

DR. MILLS: It seems to me that the States that have been out here need to get together so we can look at it.

NORM STUDIES in the STATE of WASHINGTON

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Washington Department of Social and Health Services

One of the areas of concern in the Washington Radiation Control Program is that of exposure to radiation as a result of the translocation of naturally occurring radioactive materials, or NORM. Basically, our attention has been directed toward four areas: the use of phosphate slag in the manufacturing of insulation, the disposal of low specific activity NORM, the use of zirconium sand in foundry operations, and the copper processing industry. We are in the initial states of the investigations. I will describe our findings to date in this presentation.

I would like to begin with the disposal of large volumes of low specific activity NORM in the State's commercial radioactive waste burial site. The State of Washington has been concerned that the acceptance of this waste in the Richland site constitutes the use of an essential and dwindling national resource. Governor Dixy Lee Ray issued a decision memorandum with recommendations in September 1978 concerning this matter. One of the recommendations instructed the Radiation Control Program to amend the license of the Nuclear Engineering Company. The amendment allows the Richland disposal site to receive and bury packaged dry or solid NORM wastes at concentrations in excess of 2×10^{-3} microcuries per gram or which could result in an external exposure to humans in the unrestricted areas in excess of 100 milliroentgens in any 7 consecutive days of continuous exposure.

The potential radiological impact of the copper refinery and smelter in Tacoma has been briefly examined. Approximately 25,000 tons of copper concentrate are processed each month at this facility. The smelting process results in about 200,000 tons of slag per year. The slag is used in sand blasting, fill, and as aggregates for the cement industries. A survey using a Ludlum Micro R meter of the ore concentrate pile showed a background reading. The slag pile had a maximum reading of two times background. Analysis of the copper concentrate and slag has not been completed.

Another potential NORM problem being investigated is the use of zirconium sand by foundries. Samples of the sand have been collected from a foundry and a limited radiation survey was conducted. This particular facility uses Dupont zirconium sand. During the survey, it was found that radiography was being performed so the readings may have limited value. However, the maximum readings were: zircon sand in bags - 300 uR/hr, heap sand - 150 uR/hr, alum shot in bags - 100 uR/hr, and Bentonite in bags - 100 uR/hr. Radioanalyses of the samples are not yet complete.

Most of the program's attention has been directed toward the use of phosphate slag in the manufacture of insulation. This is an example of a potential public health hazard imposed in the manufacturing process of the final consumer product. The Idaho Department of Health notified Washington Radiation Control Program that phosphate slag from Soda Springs, Idaho, or Soda Springs slag, was being shipped into the State for use in the manufacture of insulation. The production of insulation involves steel slag, basalt, and Soda Springs slag. The slag was used in the insulation manufactured from June 1973 to June 1975 and from July 1976 to July 1977.

There are three types of final products - blown wool, blanket, and industrial felt. The felt is several blankets compressed and used to insulate boilers. The distribution is essentially in the Northwest. Sales are basically made to building and insulation contractors. During the time the slag was used in the process, the demand was so great that the product was probably not stored in warehouses.

Samples of slag and insulation were analyzed by EPA, Las Vegas Laboratories. Figure 1 shows the average concentration for radium-226 ± 2 sigma counting error. The results demonstrated that radioactivity was carried from the slag to the insulation. On this basis it was decided that further study was necessary to determine the potential health problems that exist to the general population and/or workers.

Figure 1. Insulation - Ra-226 analysis - average concentration

	PCi/GM		
Soda Spring slag rock	38	±	1.1
Soda Spring slag ground-up	47	±	1.2
Basalt	0.56	±	.14
Geneva slag	2.9	±	.30
Phillips coke	0.51	±	.13
Blanket type insulation manufactured (11/76)	13	±	.67
Blown wool type insulation manufactured (11/76)	16	±	.73
Blown wool type insulation manufactured (4/78)	2.8	±	.29
Rock wool	6.6	±	.44
Fiberglass wool	0.5	±	.13

Proposal to investigate radiological health impact in housing units insulated with specific insulation

Phase I	Unit identification - activated charcoal cartridge - uR meter
Phase II	Pilot study - unoccupied unit examined with uR meter and radon progeny integrating sampling units for 3 months - an additional 3 months study may be necessary
Phase III	Selected residence study - one year study - occupied residences, if available, will be examined

The first phase is the determination of whether or not hazards exist in homes insulated with this insulation. Specifically, we want to determine whether elevated gamma radiation and radon daughter levels exist in these dwellings.

To examine this potential health problem, one convenient source of housing is that located at military installations. These units generally have similar construction and are located in large clusters. One such installation in the State of Washington has 400 units with insulation from this manufacturer. A proposal was prepared by the Department of Social and Health Services and distributed to the manufacturers, military installations, and U.S. Environmental Protection Agency for comments. The first phase will identify houses with the insulation of concern. You will recall that Soda Springs slag was used over a 3-year time period so that it is necessary to identify homes individually. One way to do this is to obtain an air sample and estimate the radon levels. The samples will be taken using an air sampler at 1.5 liters per minute and activated charcoal cartridges that will be counted by Ge (Li) or NaI spectrometry. In addition, we will use a Micro R meter to determine whether these units can be identified by gamma exposure.

Once the homes are identified, a pilot study using unoccupied units will be initiated. Gamma exposure and radon daughter levels will be measured. Radon levels will be determined using a radon daughter integrating sampling unit. The sampling facet will be conducted for a period of 3 months. On the basis of the results, the studies may be continued an additional 3 months. This pilot study will allow the examination of the worst-case basis. If the results indicate that a problem could or does exist, occupied residences will be examined. This phase, or phase three, will cover a period of 1 year.

If either the gamma measurements and/or radon daughter levels exceed the action levels, remedial action will be considered. The results may also indicate that additional units should be examined. No specific action level will be proposed at this time for two reasons. First, the final recommendation for radiation protection for the Florida phosphate lands should serve as a guide in determining these levels. Second, since the radiological health impact of the use of insulation in residences has not been studied previously, it may be premature to estimate levels at this stage. As with delineating specific action levels, it seems prudent to determine avenues for reducing the radiation exposure if required as the problem is defined.

The types of radiological health assessment of NORM problems that are being conducted by the Washington Radiation Control Program have been described. We are in the early stages of investigating these potential problem areas. It seems that, on examining NORM problems, every time you identify one problem there are several other related issues that must be addressed also.

DISCUSSION

DR. SOLON: What was identified as a national resource by Governor Ray?

DR. HAARS: The State of Washington considers the disposal site as a national resource and the use of it by the large volume low-specific activities may constitute the utilization of this, perhaps unnecessarily.

DR. SOLON: The compromise of a national resource as a result of the use of this, is that the concept?

DR. HAARS: I would phrase it that should we use this national resource, this disposal site, for a large volume of low-specific activity, is it a significant health problem to use it for that purpose.

RADIUM REMOVAL from WATER

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Division of Occupational Health, Texas Department of Health

In late 1977, the Texas Department of Health received a grant from the U.S. Environmental Protection Agency (EPA) for a demonstration scale plant for the removal of radium from drinking water. The process uses an ion-exchange medium that is highly specific for radium. There have been many delays and difficulties with the project so far, most of which involve dealing with two bureaucratic systems. There have also been problems with suppliers of materials as well as some other problems that will be discussed later. I would like to share our experiences and the indications of success that we are seeing with you today. The project is still in the initial phases, but we are now working on the phase of the project where results will be obtained rapidly. As a consequence, much of what I will discuss is based on a preliminary data interpretation and is subject to change as more data comes in and as we begin to develop some experience with the process. I will, therefore, be rather informal.

In 1973, Martin C. Wukasch and I reported the discovery of certain well waters in South Texas that contained high levels of radioactivity (1). The report was given at the Third International Congress of the International Radiation Protection Association in Washington, D.C. and the Washington Post summarized the paper. About that time our office got a call from a Dr. W. S. Moore, who was a geochemist with the U.S. Navy. He was doing research studying the mixing rates of the deep oceans, and went about this by examining the ratio of radium-228, which has a 5-year half-life, to radium-226, which has a 1620-year half-life. Any water that contained relatively high concentrations of radium-228 would have recently been in contact with sediments. Waters barren of radium-228 would have been away from bottom sediuments for 50 years or longer.

Because the concentration of radium-226 and radium-228 both are low in sea water, Wukasch had been working on a way to concentrate the radium so that he could take smaller samples. What he had developed was a fiber, an acrylic fiber, which he treated with oxides of manganese. This would effectively collect radium from comparatively large volumes of sea water.

He had seen the article in the Post and wanted to know if we would be interested in seeing if his manganese fibers would remove radium from the well waters in South Texas. Naturally, we were; so in a few weeks we tried some experiments and found that 1 gram of fiber could decontaminate 100 gallons of water to the drinking water limit, which then was 3×10^{9} μ Ci/ml.

The town of Flatonia, Texas, is a small town (population 1100) on Interstate 10 midway between Houston and San Antonio. We discovered that the water supply of the town exceeded the drinking water standard. The system was composed of four wells, and two of them exceeded 10×10^{9} μ Ci/ml. The others were just at or above the standard. We quite successfully treated water on a laboratory scale and were encouraged. To see if the manganese fibers could effectively and inexpensively remove radium from the drinking water supply of this small town, we applied for and received a grant from the United States Environmental Protection Agency. The EPA shared the costs of this test of the radium removal processing with Texas and Flatonia. EPA supplies the materials and equipment, Texas furnishes the people, and Flatonia provides support and maintenance.

The initial phases of the project involved delay after delay. The worst case was the filter housing. It is a steel vessel, which supposedly would take 6 to 8 weeks to construct. It actually took 6 months, and then during shipment, it was destroyed in a warehouse fire. A second filter housing ordered for the other well in the system was used to replace the first one. It was received and installed in November 1978. Another difficulty involved the procurement of correct filter material. The filter vessel was designed to hold 120 filters, which were acrylic fibers spun onto 1-inch diameter by 30-inch length centers. The manufacturer of the filters had substituted a different fiber that could not be treated to absorb the manganese oxides, try as we would. The fibers looked like the acrylic fibers; in fact, we did not discover the filter fibers were not acrylic fibers until after we had soaked them in increasingly strong, warm solutions of potassium permanganate. They should have turned black, but only turned beige. Once we got the filters replaced, processing went well. We very cautiously undertreated the first batch of filters because we did not want to risk further delays in getting started treating the water.

Our original contract with EPA was to last 1 year, and because of these delays, it has been extended to 2 years.

Once we got the correct filters and the filter housing installed, we began processing water. As with all projects of this type, we had hoped for perfect performance, but found the radium removal to be less than perfect. We have not yet determined why, but we are investigating. We do have some ideas. For example, we treated the fibers so they took up manganese to 5 to 6 percent by weight rather than the design goal of 7.5 to 9 percent by weight. That is probably in itself, the reason. We also thought that perhaps there was non-uniform flow through the filter housing, so we installed a baffle for redirecting the flow. We are not sure that helped.

The data is shown in Figure 1 and Table 1. The average removal of radium from the water was 79 percent. We have also develped a testing device that would test a single filter at a time. The results, shown in Table 2, indicate generally better radium removal at lower flow rates than at high flow rates, which was expected. During the passage of water through the filters, the contact time between the water and filter medium is increased at lower flow rates. There have been other problems. The most highly contaminated well was expected to produce water at about 11 by 17 x 10^{-9} μCi/ml instead of 27 x 10^{-9} μCi/ml. By the time 5 or 6 million liters had been processed, it was expected that removal efficiencies would have shown a systematic decline to less than 50 percent, but there seems to have been no systematic trend in nearly 8 million liters. Our original estimates were intended to be conservative and are proving to be so.

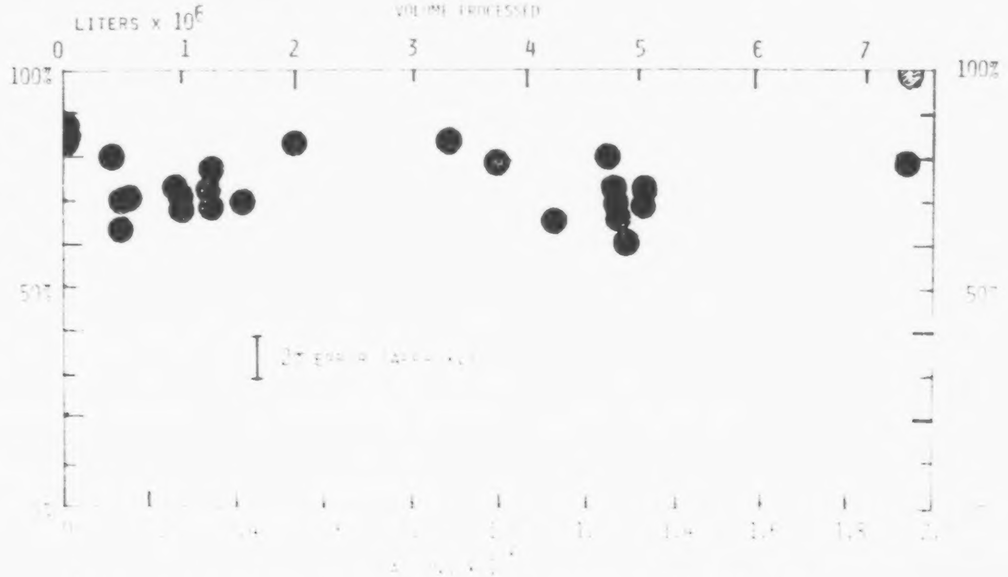

FIGURE 1. RADIUM REMOVAL EFFICIENCY VERSUS VOLUME OF WATER PROCESSED.

Table 1. Water processing results

Date	Time	Volume (gal. x 1000)	Well	Before $\mu Ci/ml \times 10^{-9}$	After $\mu Ci/ml \times 10^{-9}$	Removal %
12/05/78	1500	1	6	38	6.7	83
		4	6		6.6	
		8	6		3.6	
		6	6	28	4.0	86
12/06/78	1000	114	6	24	4.8	80
	1230	123	6	19	7.0	63
	1330	129	6	20	5.9	70
	1530	141	6	20	5.9	70
12/1178	1205	255	6	26	7.1	73
	1305	261	6	22	6.3	71
	1405	267	6	22	7.1	67
	1505	273	6	23	7.2	68
12/13/78	1406	333	6	27	8.7	68
	1416	334	6	33	7.6	77
	1446	337	6	25	6.8	73
12/14/78	0800	409	6	(27)	8.2	70
	0950	535	6	(27)	4.6	83
	0950	535	6	(27)	4.6	83
12/18/78	unkn.	(877)	6	(27)	4.4	84
12/19/78	0745	991	6	(27)	5.8	78
12/20/78	0845	1123	6	(27)	9.4	65
12/21/78	0935	1249	6	29	7.0	80
1/18/79	1300	1252	6	32	10.9	66
	1340	1256	6	40	10.8	72
1/19/79	1050	1278	6+7	17	7.5	56
	1230	1290	6+7	19	6.1	68
	1330	1304	6+7	20	5.7	72
2/06/79	1320	1962	6	37	8.1	78
	1335	1964	6+7	32	6.9	79
	1350	1965	7	17	<0.2	>98
2/13/79		1966	7	9.5	2.0	79

Table 2. Percent radium removal vs. flow rate

Rate L/Min.	Radium Removal %
2	92
4	86
8	80
16	84

As part of our conservatism, we have tested the delivered water for acrylonitrile and have not found any. Before the test results were received, we dumped the treated water on the ground. Once the negative sample results were received, we added water to the system. Since the normal treatment of the filters consists of soaking them in warm (30 °C) saturated solutions of potassium permanganate, this should oxidize any traces of chemicals left after manufacture.

The mechanism by which the manganese oxides absorb radium is believed to be ion exchange, probably with potassium. The radium can be leached off of the filters after they have ceased to function effectively using 1.5 to 2 N Nitric Acid, and the potassium content increased by a bath in a potassium chloride solution. The filters can then be rinsed and reused.

There are other subleties with the process. One is the ability of the filter to "rebound" with greater removal efficiency after being shut down for a few hours. We think there may also be a similar longer term effect.

The system has been valved "off" since mid-February. With summer, the town's heavy water use period approaching, we are scheduling the resuming of operation. We will remove the slightly used filters and replace them with the other batch, which was treated with higher amounts of manganese. We expect that the radium removal percentage will increase.

It is too early to determine what the costs of the process are, except that it appears that the costs of operation will be less than 50 cents per thousand gallons. That number is an upper limit and may be high by a factor of ten. It is one of the numbers we hope to generate in the next 3 months.

REFERENCE

1. Wukasch, M.C. and L.C. Cook. High radioactivity in drinking water and ground water in South Texas. In: Proceedings of the International Radiation Protection Association, III International Congress, Washington, D.C., September 9 - 14, 1973, pp. 272-278, U.S. AEC, Oak Ridge, Tennessee (1973).

DISCUSSION

MR. BAILEY: Several people have asked me about producing radium. Would you mind saying a little bit about what you told us about the system we are thinking about requiring the city to use?

MR. COOK: Yes. As part of the project, we are instructing the city crew on radiation safety, and it will be necessary to get a radioactive materials license, which we will assist them in obtaining, for the radium concentration and subsequent disposal. At the present time, disposal consists of shipment to a commercial burial site. It would also be possible to put waste of this nature perhaps in a uranium mill tailings pond. The additional radium put in the uranium mill tailings pond would amount to a few hours processing for a project of this size over a year.

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STATUS of CURRENT STUDIES of RADON in PUBLIC and PRIVATE WATER SUPPLIES in NEW ENGLAND

Wallace W. Hinckley
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Maine Bureau of Health

Ever since Adam found himself thrust onto this little Eden we call Earth, man has been subjected to a hostile environment. When Adam arrived, he wasn't exactly prepared for the bitter north wind or the chilling rain. He was hungry, thirsty, and his ribs felt like hell. Walking to a little glen, he found a beautiful and bountiful garden with a picturesque little well and of course Eve.

Adam dipped a cup of water from the well and quenched his thirst. Little heed was given to the sign erected by God's Surgeon General stating "Radon present, ingestion may be hazardous to your health." Adam's disregard for the dangers of low level radiation is a characteristic seemingly reminiscent of those who set radiation standards for drinking water. To be sure, what is needed is a revelation from the "GSG" advising us of God's drinking water standards. Perhaps the BEIR Committee has had such a revelation.

Radon-222 is an inert noble gas and a daughter of radium-226 in the uranium-238 decay series. Radon refers to radon-222; however, radon-220, (thoron) and radon-219 (actinon) are usually present in lesser abundance as the decay products from thorium-232 and uranium-235, respectively. Radon diffuses through the underground geological strata by atom recoil, diffusion through the rock, and saturation in the groundwater.

The first earthly standard for radioactivity in drinking water was established by the National Bureau of Standards in 1953 (Handbook No. 52). In 1959 NBS revised the standard (Handbook No. 69) with the notable deletion of the 2,000 pCi/l standard for radioactive radon plus daughter products in drinking water. It does not seem uncoincidental that this revision coincided with the discovery in Maine and New Hampshire that over half of the rural population was consuming drinking water that exceeded the standard and that water drawn from many wells was exceeding the standard by 10 to 1,000 times. Over the years, there have been reports of radium and radon occurring in the water supplies from Iowa, North Carolina, and Rhode Island. This demonstrates that the phenomenon is widespread.

The Safe Drinking Water Act (Public Law 93-523) has set a drinking water standard for radium-226 and radium-228. This standard sets a maximum contaminant level for radium of 5 pCi/l and a maximum gross alpha particle activity of 15 pCi/l from radium-226 (radium-228 is a beta emitter). Gross alpha particle activity from uranium or radon is not included in the total alpha ativity. These standards are applied to the Community Water Systems serving the metropolitan and suburban populations of the United States. The rural population in New England and some other parts of the country may be drinking water exceeding these standards.

The U.S. Environmental Protection Agency is investigating radon in water supplies because a major pathway for inhalation exposure exists in addition to the ingestion pathway. This is revealed in a paper presented by Duncan et al. in 1976. The conclusion presented in the paper, now apparently disinherited by EPA, proposed a 500-pCi/l limit for radon as a suggested standard for drinking water. Few private well water supplies in New England could meet this proposed standard.

Adorning the book shelves of State radiation programs are voluminous guides for decommissioning nuclear reactors, treating mill tailings, transporting nuclear wastes, and so forth. Conspicuously absent is the definitive work needed on the methods of controlling the effects of radiation from radium and radon in drinking water from private water supplies.

Technically enhanced natural radiation (TENR) includes those means by which man's activities contribute to exposure from natural radiation. This category of natural radiation would include exposure from underground mining, strip mining, natural gas, drinking water, and so forth. Drinking water is a less dramatic, but oft forgotten source of TENR; forgotten at least in the TENR philosophy that unnecessary, non-beneficial exposures to radiation should be avoided, whatever the source, and that cost effective control should be instituted and radiation exposure controlled or avoided. Until now, radiation in drinking water has been studied as a natural phenomenon, ignoring the health. BEIR III will obviously have implications that control of all sources of natural radiation will be necessary in the future.

Radium and radon in drinking water was one of nine problem areas addressed by Task Force No. 7 and published by the Conference of Radiation Control Program Directors in 1978 in a report on "Natural Radioactivity Contamination Problems."

The Task Force acknowledged that Federal regulations have been established for radium. It suggests that a limited amount of research has been completed on the health effects of ingesting radon daughters. The report recommends that EPA should study whole body and organ doses resulting from ingestion of radon daughters in drinking water and the inhalation of radon released from water in home and commercial use.

Five papers have been completed recently relating to the activities of State radiation control programs and their concern for high radiation exposures to families served by water supplies with high radium-226/radon-222 concentrations. These five papers are summarized below. Copies of the 5 papers may be obtained by writing to the Division of Health Engineering, State House, Augusta, Maine 04333.

1. Does Radon in Drinking Water Cause Cancer? (Maine Bureau of Health). This paper describes an attempt to determine a radon/cancer disease relationship from 9 years of computerized cancer mortality and morbidity data, and age-adjusted sample populations where drinking water is from geologic conditions typically related to high radon groundwaters was selected. A low radon sample population was used as a comparison and the relative incidence of disease was measured by a method of standard errors. Maine has a very high rate of respiratory and cancer mortality. A comparison of the high and low radon populations showed no correlation between high radon and respiratory disease. There was a correlation indicated between high radon and certain types of cancer; however, the cancer types, such as lymphatic and hemopoetic cancer in female, were those not directly effecting the ingestion and inhalation pathway. If there is a relationship between lymphatic and hemopoetic cancer in females and radon, the mechanism must be complex.

2. Radon in Potable Water Supplies in Maine (Physics Department, University of Maine). The purpose of this study has been to determine the geologic sources of radon in well water; to determine the rate of transfer of radon into air; to determine the radiation dose due to radon and its daughters; to calculate the statistical expectation of cancer and other health effects and to recommend a safe drinking water standard.

   In addition to expanding the data base on radon in water supplies by examining 350 additional deep wells for bedrock geology and radon concentration, several homes were selected for quantifying the airborne activity of radon in equilibrium with radon daughters and the effect of radiation exposure on the respiratory system.

3. Naturally Occurring Radioactivity in Vermont's Drinking Water (Vermont Department of Health). This paper summarizes the current knowledge of the health effects of radon in drinking waters. The results of radon concentrations performed on several water supplies in Vermont by the Eastern Environmental Radiation Facility of EPA in Montgomery, Alabama, are listed as well as New England radon in water concentration data and all States radon and water concentration data (excluding the New England data).

4. Natural Radiation in the Drinking Water of Rhode Island (Rhode Island Department of Health). This paper describes the discovery of radium and radon in the water supply of a nursing home in Rhode Island. This supply contains the highest radon concentration found in New England to date. Radon-222 is measured to be 250,000 pCi/l and Radium-226/228 was measured to be 430 pCi/l of radium. An interesting adjunct to the study is the location of a water softener in the water system of the nursing home that entraps radium. Radiation measurements of the ion exchange resins indicate radioactivity measures 10 mr/hr at a distance of 1 ft from the water softener.

   Rhode Island Radiation Control Program has had 54 water supplies from deep wells analyzed. Seventeen percent of the samples exceed a concentration of 10,00 pCi/l and only 4 percent are below the 500-pCi/l standard recommended by Duncan. The relative risk for ingestion of radon daughters was compared with the risk acceptable under the Federal drinking water standards for radium. The risk from drinking water with 10,000 pCi/l radon-222 was calculated to be equivalent to the effects of drinking water at the current radium-226/228 limit.

5. Is Inhalation the Critical Pathway for Radiation Exposure from Radon-222 in Potable Water Supplies? (Maine Bureau of Health). This paper reviews previous studies of Duncan and Gesell and compares their results with new data from actual measurements in homes and schools and relates it to radon dosimetry for the inhalation pathway. These results are expressed in Working Levels (WL) from which relative risk is compared for varying structural conditions.

   Working Levels measured are compared with the Surgeon General's action guidelines for dwellings constructed on uranium mill tailings and the risk factors projected for dwellings constructed on reclaimed phosphate land.

   The analysis of the data reveals that ingestion is the critical mode of exposure. A comparison of the inhalation pathway and relative risks indicates that a radon-in-water standard of 25,000 pCi/l may be tolerable, however, the paper presents ingestion as the critical pathway.

The reported inclusion of excess cancer deaths in the BEIR III report, released on May 2, by the National Academy of Sciences will undoubtedly stir this Conference and its Federal cooperators to expeditiously implement a reasonable drinking water standard and establish methods of treatment for community and non-community water supplies based upon cost-benefit analyses as defined in BEIR II. The bibliographic information included with the above mentioned reports indicates that there is sufficient information to support adoption of a recommended standard. What are we waiting for?

DISCUSSION

MR. DUNCAN: I would like to say that I do not remember it being a proposal, but merely an example that was used originally in the paper.

MR. HINCKLEY: One of the problems is that a lot of your information was published in at least two places and the EPA Annual Summary Data. I know there has been some question whether this was a preliminary research. It does get published where people can see it and make inferences from it that it is something EPA is going adopt. I think you can appreciate --and I have seen that in every one of the studies in New England--that the reference is used repeatedly as being a suggestion, EPA is considering a standard.

MR. DUNCAN: I wish to correct that. It was merely an example of a situation in which if one had 500 pCi per liter in the water, what would one expect as inhalation exposure. At least the papers I represented were putting forth the recommendation stated as a recommendation.

MR. HINCKLEY: I think you will see in our table-clinic that we are concerned with any standard less than 10,000 picocuries per liter. I think that probably the things we are looking at, risk-cost benefit type things and how many wells are we going to have to treat, if it is less than this.

MR. DUNCAN: That paper was merely to get people to look at the problem. It was certainly not projected as a standard-setting document.

MR. GALPIN: It was a thought-stimulation paper and I am glad it stimulated some thought. I think some comment on what EPA is doing is desirable in that we have not forgotten about radon and water. Indeed the studies that are being initiated by ERG in terms of sending out vials and getting samples has filled data base, so that we have some legitimacy to do something other than give each State a guide at a time and to do something on a National basis. Also, I point out, that in the Drinking Water Act you are not allowed to utilize anything other than the ingestion pathway, impact through the ingestion pathway, as a risk in the context of that pathway. I will consider the inhalation pathway to include the water supply.

DR. LAPENBUSH: We plan to come up with some sort of regulations for uranium and drinking water and that is with the help of the National Academy of Sciences and Health Radiation Programs. We also plan to do something about radon, but before we do we have to get an appreciation of the relative sources of contribution.

RADIOACTIVITY ASSOCIATED with SELECTED MINERAL EXTRACTION INDUSTRIES

Donald W. Hendricks and Vernon E. Andrews
Office of Radiation Programs/Las Vegas Facility
U.S. Environmental Protection Agency

As you have heard from the previous speakers, the mining, milling, and processing of mineral resources can and does cause enhanced levels of natural radioactivity in products and wastes in a number of minieral extraction industries. Our Las Vegas Facility of EPA's Office of Radiation Programs has been conducting both field studies and literature reviews in an effort to identify these industries and to quantify the associated radioactivity levels. We expect to use the information gained to set standards under the Clear Air Act and the Resource Conservation and Recovery Act.

We began with a literature search (1) by one of our staff geologists. A condensed summary of his findings is shown in Table 1. Based on those findings and other data, several mineral industries were selected from the list in Table 1 for sampling and evaluation.

Commodities to be included in the studies were selected on the basis of their potential to emit dosimetrically significant quantities of naturally occurring radionuclides to the atmosphere. Factors in the selection included typical mine size, annual U.S. production, measured radon daughter working levels in underground mines and associated ventilation rates, production rate and process employed by individual facilities, and historical association with naturally occurring radionuclides. In general, the larger facilities of a given commodity were selected in order to improve the chance of collecting sufficient radioactivity to be able to make a reasonable estimate of the fractions emitted.

The intent of the studies has been to determine the signficant points of airborne releases of the radionuclides of interest for the various mining, milling, beneficiation, smelting, or other processing steps of the commodities surveyed. If emission controls are found to be necessary for any commodities, the most important sources can be identified and the most effective controls, therefore, applied. To the extent possible, ore and process samples were also collected for analysis.

The nuclides evaluated were radon gas; uranium-234, uranium-235, and uranium-238; thorium-228, thorium-230, and thorium-232; radium-226; lead-210; and polonium-210.

Tables 2 and 3 show the commodities and States selected for initial sampling.

Both mines and processing facilities are being sampled. In addition to sampling mine vents, plant stacks, and process streams, where possible, we have also made radon exhalation measurements using charcoal canisters on waste piles. Table 4 shows the general types of sampling performed. In Figure 1, you can see for an elemental phosphorus plant the type of mass balance we would like to be able to perform to know how the radionuclides move through a given plant. However, since we are sampling primarily using our Clear Air Act Authority, we are not going to be able in all cases to get enough information for a complete mass balance. Note that the principal airborne radionuclide emission is polonium-210. This study (2) was done some time ago by our facility. Preliminary results of some of our current studies are shown in Tables 5 and 6. All of our samples are not yet analyzed so this summarizes much of our available data.

Note in Table 5 we are showing polonium-210 as the principal radionuclide emitted from the plants. This seems to be the case wherever we encounter kilns, furnaces, ovens, or calciners. By comparison, the annual polonium-210 release from the elemental phosphorus plant mentioned earlier was about 7.4 curies.

Table 1. Mineral extraction industries known or believed to involve enhanced levels of natural radioactivity.

Metals		Non-metals
Aluminum	Nickel	Clays
Beryllium	Rare-Earth Elements	Coal
Columbium (niobium)	Silver	Fluorspar
Copper	Tantalum	Granite
Gold	Thorium	Lime
Iron	Titanium	Phosphate
Lead	Uranium	
Molybdenum	Zinc	
	Zirconium	

Table 2. Mineral extraction industries - radiation field studies.

Commodity		Location	Initial visit	Sampling visit
Zinc	Mine (UG) Smelter	Pennsylvania	6/5/78 6/7/78	9/25 - 9/29/78 10/2 - 10/12/78
Limestone	- Mine (UG) Mill	Illinois	6/8/78	1/8 - 1/18/78
Clay	- Mine (UG) Mill	West Virginia	6/2/78	8/7 - 8/11/78
Copper, Zinc, Iron	- Mine (UG) Pellet Plant Smelter	Tennessee	5/31/78	1/29 - 2/2/79
Iron	- Mine (UG) Mill Pellet Plant	Missouri	7/18/78	10/16 - 10/27/78

Table 3. Mineral extraction industries - radiation field studies planned.

Commodity		Location
Iron	Mine (open pit) Mill Pellet plant	Michigan
Copper	- Mine (open pit)	Montana
Clay	- Mine (open pit)	Texas
Aluminum	- Mine (Open pit) Plant Reduction plant	Arkansas
Fluorspar	- Mine (UG) Crystal mill	Illinois
Phosphate	- Mine (UG) Thermal plant	Montana
Tungsten	- Mine (UG & open pit)	Not selected
Lead	- Mine (UG & open pit)	Not selected
Molybdenum	- Mine (UG & open pit)	Not selected
Phosphate	- Mine (open pit) Wet acid plant	Not selected

Table 4. Mineral extraction industries sampling

UNDERGROUND MINES

Ventilation exhausts - ^{222}Rn, particulates, particle size
In mine - radon progeny working level

OPEN PIT MINES

^{222}Rn exhalation, downwind ^{222}Rn, downwind particulates and particle size

MILLS, BENEFICIATION PLANTS, SMELTERS

Stack sampling - ^{222}Rn, particulates, particle size
Fugitive emissions from roof monitors - ^{222}Rn, particulates
Waste piles - ^{222}Rn exhalation, downwind particulates and particle size

ALL FACILITIES

Ambient ^{222}Rn, ambient particulates
Process samples related to specific emissin points

NOTE - Air filters and process samples analyzed for $^{234, 235, 238}$U, $^{228, 230, 232}$Th, ^{226}Ra, ^{210}Pb, and ^{210}Po

Table 5. Underground mines and related facilities
Annual emissions (curies).

	Mine	Mill		
Commodity (State)	Radon	Radon	Pb-210	Po-210
Limestone (Illinois)	0.6	-	-	-
Fire Clay (West Virginia)	15	-	-	0.022[a] (0.051)
Iron (Missouri)	74	2.3	0.15	2.2
Zinc (Pennsylvania)	116	-	-	0.007

[a] Two of three kilns were equipped with ionizing wet scrubber. Not usual for brick industry. Quantity in parentheses is estimated release with no scrubber.

In Table 6, note the amount of radon reduction achieved by covering the tailings with 3 feet of clay and then vegetating. This is of interest in view of some of the methods being considered for uranium mill tailings stabilization. Also note the radium-226 levels in the iron, sand pile, and tailings.

Table 7 shows a relative ranking for the radon release per ton of ore mined. Because production data is considered confidential for some of the industries, I have not shown the actual release figures. We can say that the values for the commodities shown do cover about two orders of magnitude.

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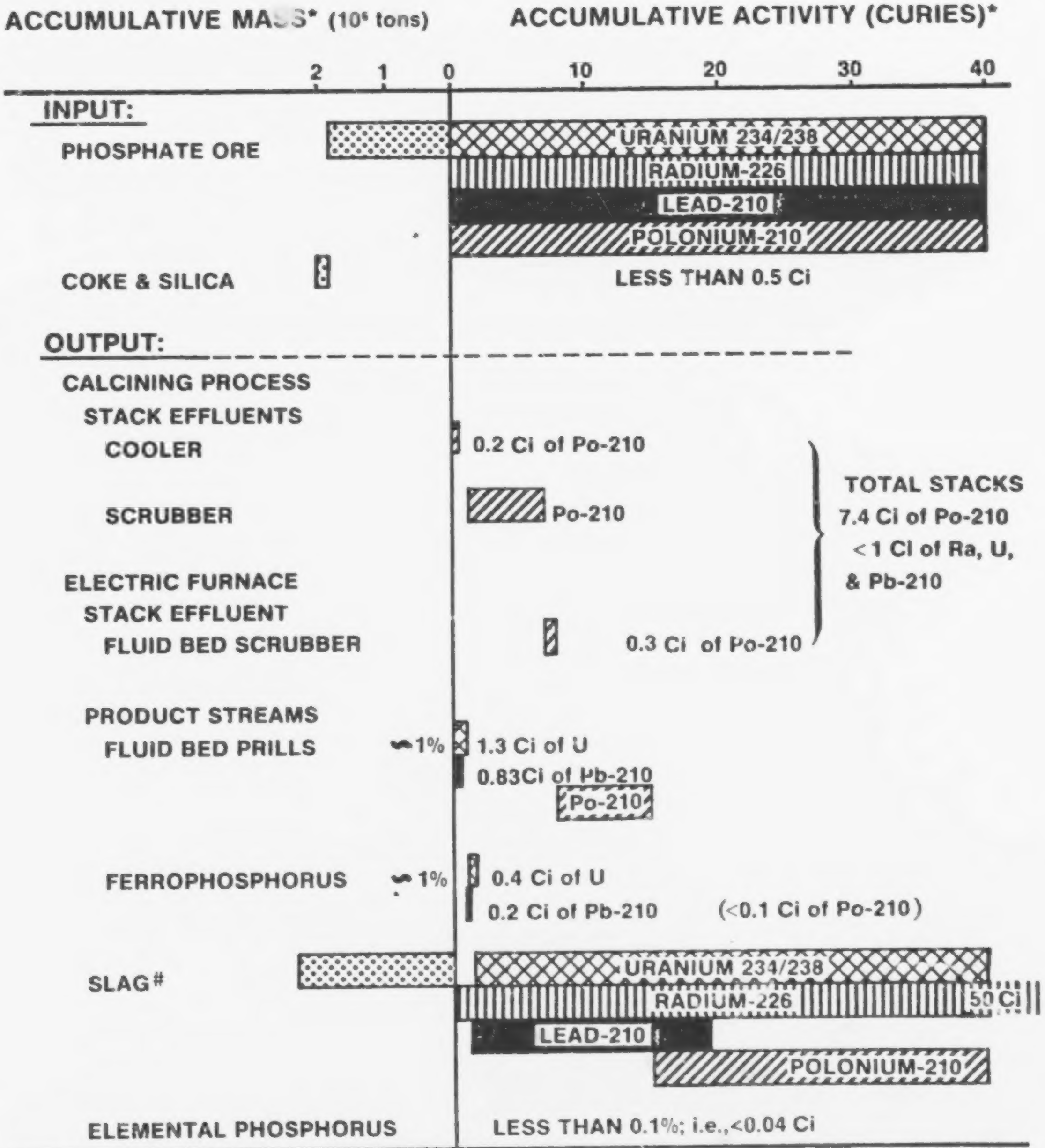
1. Bliss, J.D. Radioactivity in Selected Mineral Extraction Industries - A Literature Review. ORP/LVF-79-1, USEPA, Office of Radiation Programs, Las Vegas Facility, Las Vegas, Nevada (1978).

2. Radiological Surveys of Idaho Phosphate Ore Processing - The Thermal Process Plant. ORP/LVF-77-4, USEPA, Office of Radiation Programs, Las Vegas Facility, Las Vegas, Nevada (1977).



* THE INPUT AND OUTPUT VALUES ARE INDICATED AS ACCUMULATIVE VALUES. THUS, SUBSEQUENT ENTRIES ARE ADVANCED ALONG THE SCALE TO INDICATE THE SUM-TOTAL FROM PREVIOUS ENTRIES. ACCUMULATIVE OUTPUT VALUES IN EXCESS OF THE INPUT VALUES REFLECT UNCERTAINTIES IN THE ANALYTICAL AND MASS FLOW DATA.

# THE SLAG Po-210 VALUE IS BASED ON A LESS THAN VALUE OF 16 pCi/g (i.e., ALTHOUGH ANALYTICAL RESULTS INDICATE THE PRESENCE OF Po-210 IN THE SLAG, THE INDICATED MASS BALANCE VALUE HAS AN UNCERTAINTY APPROACHING 100 PERCENT

Figure 1

Table 6. Radon emissions from waste piles

Commodity (State)	Material	Ra-226 Conc (pCi/g)	Radon emission rate (pCi/m^2/min)[a] Waste pile			Pile depth (ft)
			Uncovered	Stabilized	Background	
Zinc (Penna)	Tailings (limestone)	0.22	5.8±3.1 (1.9-11.3)	7.7±1.7[b] (6.0-11)	15±7.8 (4.7-27)	∼30
	Briquet residue (smelter)	1.6	13±12 (3.4-35)		22±10 (8.2-30)	50-100
Iron (Missouri)	Sand pile	5.0	63±18 (46-87)		46±33[c] (17-82)	30
	Tailings	6.3	72±17[d] (59-84)	12±6.6[e] (3.4-19)	24±13[c] (11-37)	∼50
	Chat pile	3.1	3.3±0.9 (2.9-4.1)			10

[a] Range in parentheses

[b] Covered with local topsoil and vegetated

[c] Average of backgrounds at iron facility = 35±25 (11-82) throwing out highest and lowest result background = 30±10 (17-40)

[d] Two samples

[e] Covered with ∼3 ft of clay and vegetated

Table 7. Radon release per ton of ore mined (Relative ranking[1])

LIMESTONE
FIRE CLAY
IRON
ZINC

[1] Release per ton increasing downward

DISCUSSION

MR. LLOYD: I wonder if the EPA has done any stack testing at the phosphate plant for radon-222 or if you plan to do some.

MR. HENDRICKS: I think we do have some phosphate plants on the list, but we want to go back and look at some of them again. We had a considerable amount of problems a few years ago with our polonium values, so we might want to look at that again for both the polonium and the radium.

MR. LLOYD: We strongly suspect that the radon is probably being totally driven out from the ore at the time of smelting. Last spring I took some measurements in a small community within about a mile of the Stauffer plant nearby. The ambient levels were running right at 0.02 working levels ambient to the plant, and within the plant confines inside of the office building I was measuring something like 0.006 levels. It appeared at that time that I was just getting inside the plume at the industry, while a mile away the plume was coming down to the ground. We are very suspicious, and we are seeing some really high radon contamination from these stacks.

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MR. HENDRICKS: The individual processing in these plants does all kinds of strange things. For instance, Vern, I think, is convinced that at one of the brick plants where the clay is pressured, there is probably sufficient pressure placed on the clay that you could squeeze the radon right out of the brick even though otherwise that might not happen. Some of the high radon emissions from some of the mines appeared to be associated with mine water. There is a tremendous amount of mine water produced and so many variations that the radon may be coming from the mine water instead of from the walls of the mine.

MR. DUNCAN: Some of the early work done in the tailings plant, downwind you had a higher working level concentration because of the aging of the radon. Immediately at the plant, perhaps, you are not seeing enough aging to increase your working level in relationship to the radon concentration. The radon concentration might still be higher, but you do not have any until a mile downwind where you would have a buildup.

MR. HENDRICKS: We will have working level on some of these mine exhausts and things like that. Some of them do have enough hold up within the mine to build up to be near equilibrium before it is exhausted.

The ROLE of the BUREAU of RADIOLOGICAL HEALTH in NARM EVALUATION

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The "Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)" were developed by the Conference of Radiation Control Program Directors in 1976 and published in July 1977. The BRH helped in this endeavor as did the NRC and EPA. Since then, CRCPD Task Force No. 1 has proposed two new additions for inclusion in the NARM Guides; namely, "Standard NARM Licensing Conditions" and "On-Site Surveys of Manufacturers, Assemblers, or Distributors of NARM Products." There will continue to be amendments to the NARM Guides in future years. Work still needs to be done to evaluate previously identified NARM products and to continue with the identification of new NARM products and models. As is currently the case, the overall process of product identification and evaluation, facility survey, recordkeeping, and information transfer will be a cooperative State-BRH effort.

Although an example of NARM assistance can be traced back as early as 1923, when a PHS physician was investigating the effects of radiation on persons who measured radium preparations at the National Bureau of Standards, one of the Bureau's earliest roles in NARM evaluation was that of assisting States and other Federal agencies with the safety assessment of NARM devices by examining design and construction drawings, and the review of handling and operating instructions.

Acting under Section 311 of the PHS Act (42 USC 243), the Bureau can provide assistance to the States to control radiation by reducing unnecessary exposure from radiation sources.

In the 1960's the PHS assigned radiological health engineers and specialists to work with the health departments of several States. Some of the assistance performed by State assignees involved radioactive materials; particularly radium. Notably two reports of these experiences with radium sources were published. These are the "Georgia Radium Management Project" and "The Survey of Medical Radium Installation in Wisconsin."

An instance of BRH product evaluation assistance was to Oklahoma in 1970 for the safety assessment of a portable thickness gauge containing radium. Certainly this assistance must be regarded as one of the first cooperative evaluations of a NARM product.

Much of the early history as it relates to radioactivity in consumer products was provided at the 1977 symposium on this subject and may be found in the symposium report under the title "Activities and Accomplishments of the Bureau of Radiological Health in Controlling Radioactivity in Consumer Products." This report cites Bureau analysis and evaluation of radium in the form of sealed sources, luminous compounds, powders and tablets, extensive radium-radon surface contamination of a private dwelling, radium dial pocket watches, alarm clocks, anti-static devices, electron tubes, contaminated radioactive jewelry, ceramic tableware, and natural uranium dental porcelains. The Bureau has also evaluated radium sources for gas chromatographs, dew pointers, smoke detectors, level and fill gauges, density moisture meters, and the now extinct "Genuine Radium Ray Spotter" button. Since some NARM products contain accelerator-produced radionuclides such as cadmium-109, cobalt-57, gold-195, and sodium-22, the BRH has assisted in the evaluation of RIA kits, flood sources, line phantoms, imaging phantoms, pointer sources, flexible markers, spot markers, rulers, disc sources, rod sources, simulated liquid-in-vial sources, and fluorescence excitation sources for portable lead detectors.

During the mid 1960's the Radioactive Materials Investigation Section of the Southeastern Radiological Health Laboratory researched commonly used leak test procedures to promote uniformity in the interpretation of data resulting from leak testing industrial and medical radium sources.

Seven States - Illinois, Maryland, Massachusetts, Minnesota, Missouri, Ohio, and Wisconsin have been directly assisted over the past several years with the performance of onsite surveys of NARM product manufacturers, assemblers, or distributors. The typical onsite survey includes review of records for radioactive materials control, observation of device or source assembly procedures, quality control checks, examination of product drawings and procedures for making radiation measurements and leak tests for source integrity.

The Bureau assists States and others with advice on licensing or authorizing the use of distribution of NARM products. In some cases, such assistance is suggesting or classifying the control level of the product. The distribution and use of evaluated NARM products are classified into 1 of 3 levels of control: specific license, general license, or exempt from licensure. Note that the manufacture, assembly, or importation of the product is not exempt from licensing; rather some products (e.g., ICSD, RIA kits), the manufacture of which has met the NARM Guides, are permitted distribution and are exempt from further regulatory control.

Neither the BRH nor any other Federal agency licenses the manufacturer of a NARM product for the possession and use of the radioactive material as this is performed by the States. However, BRH does recommend that all States establish and execute a NARM licensing program. Presently, 31 of the States including the District of Columbia have licensing programs for NARM. Also, the Bureau will assist in monitoring the distribution and use of NARM products, particularly those recommended for "exempt" distribution, since the use of these products does not receive any inspection or review after leaving the site of manufacture or assembly.

The Bureau coordinates information for the NARM Guides, the Radioactive Materials Reference Manual, and NARM aspects of Part C of the Suggested State Regulations for Control of Radiation. Availability of the NARM Guides was announced in the FEDERAL REGISTER on April 4, 1978, and interested persons were invited to submit written comments and recommendations regarding the document.

All the NARM product evaluations that are performed by the States and the BRH are issued for inclusion in the Radioactive Materials Reference Manual (RMRM). This manual is a catalog of information on products and uses for administrative applications by State radiation control directors in making regulatory decisions on products containing NARM. The RMRM was first developed about 1970 in cooperation with State radiological health personnel. Three kinds of RMRM transmittals are periodically issued, these are:

1. "Evaluations" whose recommendations indicate product acceptability;

2. "Product Identifications" declare the existence of a NARM product; and

3. "Advisory Notices" request that regulatory action be applied to a specific NARM product.

All State and Federal radiological health agencies may contribute information for the RMRM. Approximately 350 transmittals which evaluate, identify, or advise on NARM products or services available in the United States, have been issued. At least 24 States have contributed NARM product information to the RMRM.

The Bureau will continue to prepare, scrutinize, amend, and issue evaluations, and other transmittals for the RMRM. Also each of the NARM product manufacturers is sent a copy of the evaluation, product identification, or advisory notice for his product that is issued via the RMRM.

The Suggested State Regulations for Control of Radiation (SSRCR) was first published in 1962. The 1978 SSRCR's were prepared by the Conference, EPA, NRC, and the PHS. Currently, there are 10 main chapters or parts to the document marked A through J. Part C is entitled "Licensing of Radioactive Material" and treats all subcategories of radioactive material.

The latest revision to Part C incorporated several regulatory provisions for the manufacture, assembly, and distribution of NARM and the "Licensing State" definition. A "Licensing State" is a State with equivalent regulations as Part C and an effective program for the regulatory control of NARM. The incorporation of "Licensing State" definition is a most significant amendment since these SSRCR's have long advocated that radioactive materials be licensed. The Bureau supports the Licensing State concept and has offered to assist the Conference with program review aspects for these States.

Even with the appropriately designed NARM sources and devices that meet requirements and recommendations of the ANSI, NCRP, or NARM Guides and with capable operators or users, accidents happen occasionally exposing individuals to unplanned levels of radiation. All incidents alleged or otherwise involving human exposure to radiation from NARM sources should be reported to the Radiation Incidents Registry of the Bureau of Radiological Health.

The Bureau maintains a program on the uniform NARM control for the safe use of naturally occurring and accelerator-produced radioactive materials, and assists the States in developing and improving certain elements of a uniform State NARM program. These elements are (1) product evaluations using the NARM Guides, (2) uniform regulations for NARM via the SSRCR's, and (3) current radiologic data and safety information on NARM products and services issued in the RMRM. Hence, another aspect of the Bureau's role in NARM evaluation is the distribution and coordination of the respective information for the SSRCR, RMRM, and NARM Guides. Within FDA, the Bureau of Radiological Health coordinates NARM information with the Bureau of Medical Devices, Bureau of Drugs, and the Office of the Executive Director of Regional Operations. The Consumer Product Safety Commission, Environmental Protection Agency, National Bureau of Standards, Nuclear Regulatory Commission, and Occupational Safety and Health Administration are other Federal agencies with whom the Bureau coordinates NARM information. Of course, NARM information is also coordinated with the State and local radiation control programs.

Passage of the Medical Devices Amendments to the Federal Food, Drug, and Cosmetic Act in 1976 has brought new authorities to the Food and Drug Administration. Consequently, the Bureau of Medical Devices (BMD) and the Bureau of Radiological Health have been assigned certain duties and responsibilities for the regulation of medical devices. This brings a new role to the BRH, namely that of lead Bureau for radiation-emitting medical devices and related accesseries. The coordination of these duties and responsibilities is described in the document entitled "Working Relationships Between the Bureau of Radiological Health and the Bureau of Medical Devices." These relationships became formally effective on April 24, 1979. Therefore, BRH assumes responsibility for assuring the safety and effectiveness of medical devices containing NARM. This responsibility extends to medical devices using radioactive materials and related accessories except nuclear powered pacemakers and in vitro kits.

Some of the programs for radioactive medical devices that BRH will implement independently are:

1. Surveillance, compliance, and regulatory actions that involve misbranded or adulterated devices.

2. Seizures, prosecutions, injunctions, and regulatory letters.

3. FDA and firm-initiated recalls.

4. Promulgation of performance standards.

5. Surveillance, compliance, and regulatory actions enforcing performance standards.

6. Nonregulatory aspects of medical devices containing radioactive materials, such as education programs directed at users, participation in voluntary standards organizations, and so forth.

7. Government-wide quality assurance programs for medical devices with radioactive materials.

Some NARM medical devices for which BRH is responsible are: tubes, needles, plaques, seeds, manual and remote systems used for brachytherapy, flood/source phantoms, sealed calibration sources and radionuclide dose calibrators, test pattern phantoms, radionuclide generators, and rebreathing systems used for nuclear medicine. Many and probably most of these NARM products will be Class II medical devices and therefore will be required to meet a performance standard. Incidently, Class I medical devices are those that are safe and effective under minimal general controls and Class III devices would have to meet premarket approval requirements. Since there are literally hundreds of models of medical devices that emit gamma photons, neutrons, RF, ultrasound, laser beams, microwaves, infrared, UV, x rays or charged particles, the BRH is developing a priority system for these products. Those products rated as high priority will receive the earliest attention for standards development. However, in developing standards for such products, BRH is most likely to go the voluntary standards route initially and enlist the assistance of interested professional standard groups. Also, a single "umbrella" standard covering several somewhat similar devices simultaneously is another possible route. The intent of FDA to undertake developmental action on such standards must be announced in the FEDERAL REGISTER.

Other FDA programs for radioactive medical devices will be jointly implemented by both BRH and BMD. These joint programs pertain to banned devices, premarket notifications and approvals, classifications and petitions for reclassifications, investigational device exemption requests, records and reports, and enforcement of Good Manufacturing Practices (GMP) regulations. GMP inspections may well present BRH the first opportunity to take action on NARM medical products under the Medical Devices Amendments of 1976. As NARM medical device manufacturers are routinely inspected by FDA field offices, BRH could assist with resource personnel in performing a GMP inspection of device assembly techniques, quality control procedures, labeling aspects, and records examination. Furthermore, until performance standards are developed for NARM medical devices, the BRH will continue to recognize State evaluations of NARM products that meet the criteria of the NARM Guides.

The Bureau of Radiological Health and its predecessor organizations have provided leadership in assessing and evaluating NARM sources and devices over the past few decades. BRH has cooperated with the States, the Conference, and other Federal agencies in developing the SSRCR, RMRM, NARM Guides, and other technical reports pertaining to NARM control and the evaluation of NARM sources and devices. The BRH will continue to fulfill these roles in assisting, advising, coordinating, and implementing medical device responsibilities regarding the uniform control of naturally occurring and accelerator-produced radioactive materials.

The CONDOS METHODOLOGY for EVALUATION of RADIATION EXPOSURE from CONSUMER PRODUCTS

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Requests to incorporate and to distribute radioactive materials in products intended for unrestricted use by the general public must be evaluated carefully by agencies with the appropriate regulatory authority. In the case of naturally occurring and accelerator-produced radioactive materials (NARM), the States are the regulatory agencies. Recognizing this, the Conference of Radiation Control Program Directors, Inc. established a Task Force to develop guidance for each State's evaluation of products containing NARM. This Task Force is about to prepare a guide for evaluation of such products and is considering use of a systematic methodology, called CONDOS, to make the evaluations. The purpose of this paper is to describe the CONDOS methodology, that is, what it does, how it operates, and what it has been, and can be, used for.

The CONDOS methodology is a tool for estimating radiation doses to man from exposures to radionuclides incorporated in consumer products. It consists of two parts: (1) an outline, checklist, and selected data for modeling the life span of a product or the material from which it is made; and (2) a computer code that uses the life-span model to calculate radiation doses to exposed individuals and population groups. Part 1 of the methodology has been described previously, and both parts will be described in the final report on the methodology (1, 2).

As illustrated by Figure 1, a consumer product may proceed from manufacture to ultimate disposition via many possible pathways. The product is manufactured; distributed by one or more agencies; used in the intended manner and, possibly, in some unintended ones; discarded; and disposed of or recycled. Transportation methods interlace the entire life span and accidents are always possible.

The CONDOS methodology is designed to take the chaotic picture of Figure 1 and convert it to the organized, but flexible, scheme depicted in Figure 2. The first row of boxes represents information collection. Rows two through six represent use of the information to construct a life-span model for the product. The remaining boxes represent operations performed by the computer code.

All available information about the product to be evaluated should be collected from all possible sources (e.g., from manufacturers, distributors, retailers, and users). Information will include factual data, informed testimony, opinion, and wishful thinking. In addition, a useful guide is available for modeling transportation and distribution (3). All information must be analyzed and synthesized by the modeler into a manageable, realistic model that represents the complicated life span of a consumer product.

The modeling procedure prescribed by CONDOS is outlined in Figure 2 and illustrated in Table 1 for a hypothetical tableware product. (Numerical values are given in Table 1 and 2 only for illustrative purposes; they are not the result of an actual assessment.) A product's life span is divided into a series of rather general categories called states (Fig. 2 lists five in row two and Table 1 lists four, as the leftmost entries). These, in turn, are divided into more specific categories, called substages (row three, Fig. 2 and second leftmost entries, Table 1). The groups of persons involved in each substage are then identified and quantified (row four, Fig. 2 and third leftmost entries, Table 1). Finally, specific, representative

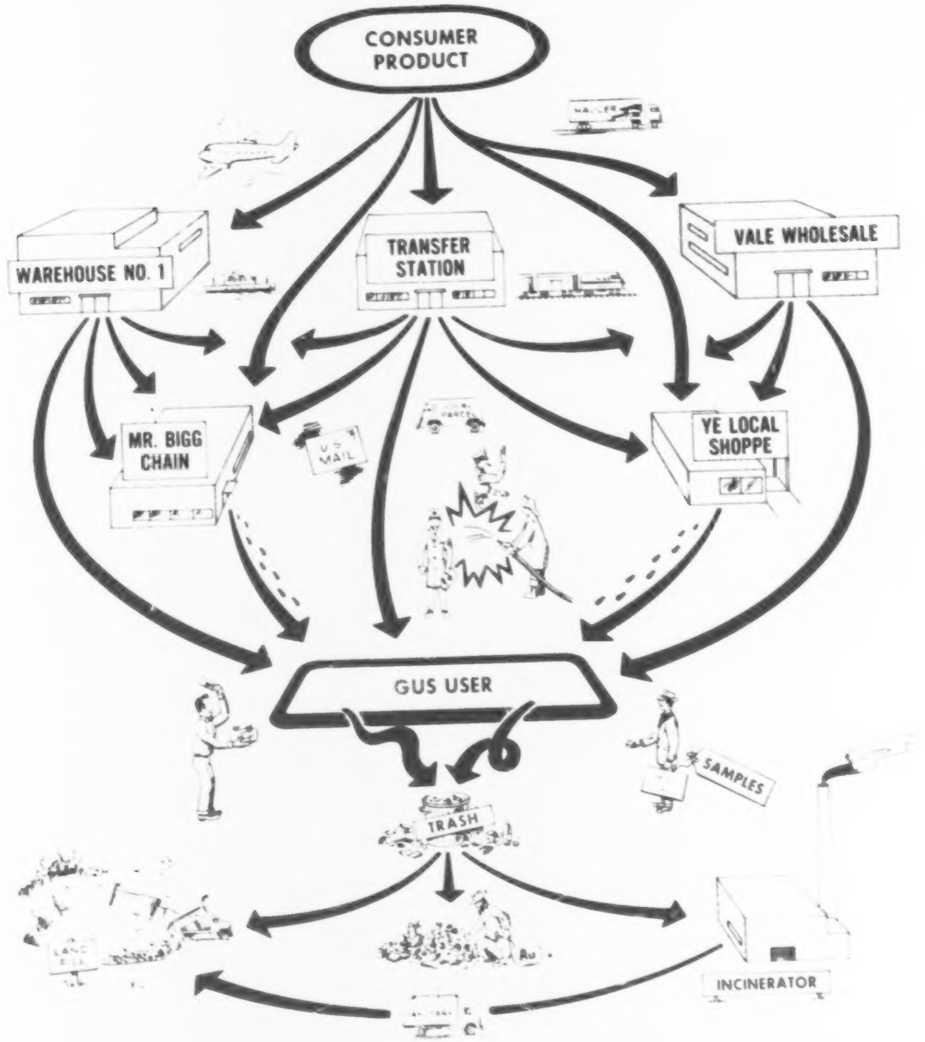
CONSUMER PRODUCT
WAREHOUSE NO. 1
TRANSFER STATION
VALE WHOLESALE
MR. BIGG CHAIN
U.S. MAIL
YE LOCAL SHOPPE
GUS USER
SAMPLES
TRASH
LAND FILL
INCINERATOR

Figure 1. The life of a consumer product.

events during which group members may be exposed to the radionuclides in the product are indentified and the conditions under which the exposures may occur are defined (row five, Fig. 2 and the remainder of Table 1).

Table 1 contains four stages, each having one substage and several groups of persons who are assumed to be exposed during one event (truck drivers and helpers were assumed to have participated in three events). In practice, a model can contain any numbers of stages, substages, groups, and events; the numbers chosen would be limited only by practical considerations. This point is illustrated in the applications of the methodology cited below.

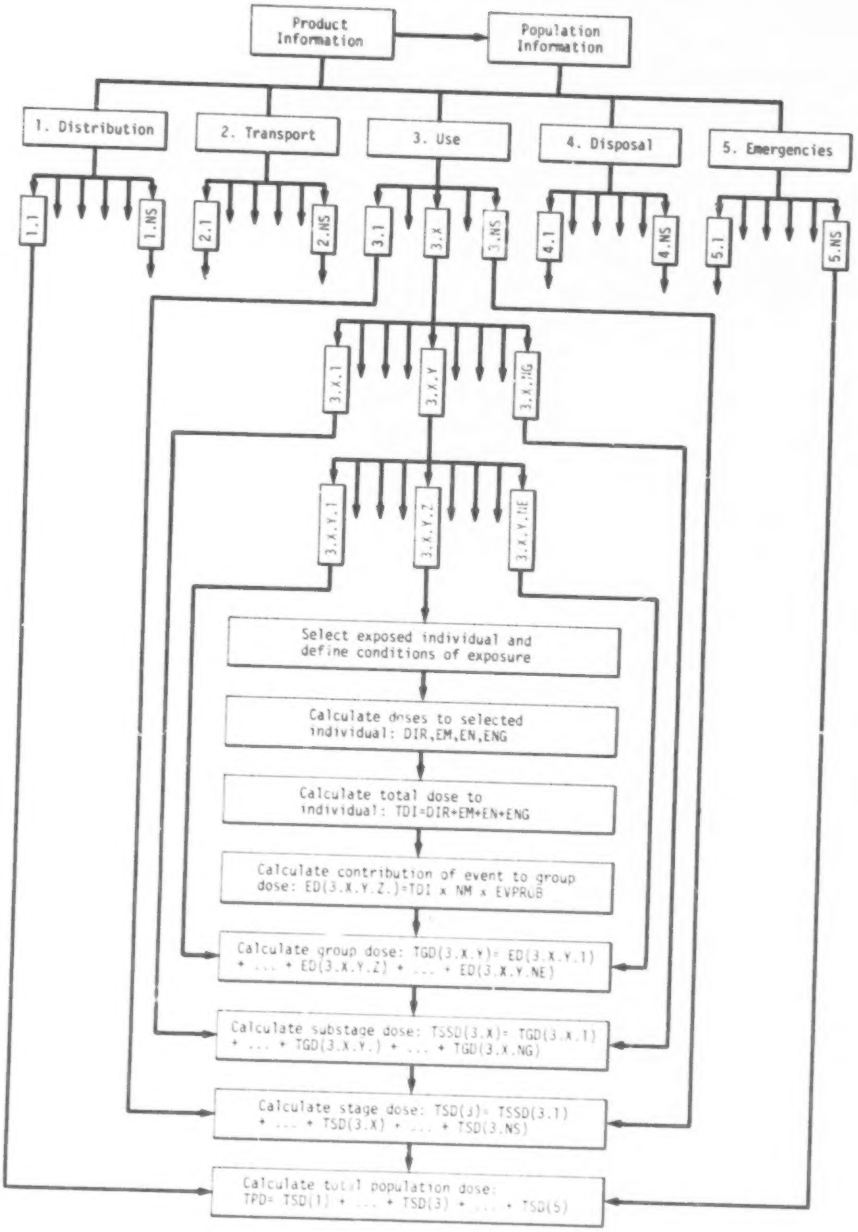
Product Information
Population Information
1. Distribution
2. Transport
3. Use
4. Disposal
5. Emergencies
1.1
1.NS
2.1
2.NS
3.1
3.X
3.NS
4.1
4.NS
5.1
5.NS
3.X.1
3.X.Y
3.X.NG
3.X.Y.1
3.X.Y.Z
3.X.Y.NE
Select exposed individual and define conditions of exposure
Calculate doses to selected individual: DIR,EM,EN,ENG
Calculate total dose to individual: TDI=DIR+EM+EN+ENG
Calculate contribution of event to group dose: ED(3.X.Y.Z.)=TDI x NM x EVPROB
Calculate group dose: TGD(3.X.Y)= ED(3.X.Y.1) + ... + ED(3.X.Y.Z) + ... + ED(3.X.Y.NE)
Calculate substage dose: TSSD(3.X)= TGD(3.X.1) + ... + TGD(3.X.Y.) + ... + TGD(3.X.NG)
Calculate stage dose: TSD(3)= TSSD(3.1) + ... + TSD(3.X) + ... + TSD(3.NS)
Calculate total population dose: TPD= TSD(1) + ... + TSD(3) + ... + TSD(5)

Figure 2. Flow chart of the life-span model and the dose calculations used in CONDOS

When modeling is completed, the computer code uses the event descriptions to calculate radiation doses to individuals participating in the selected events (rows 7 and 8, Fig. 2). Doses are calculated separately from two external and two internal exposure modes. External exposures include those from photons emitted directly from an integral product (DIR) and those from photons emitted by airborne radionuclides that may have escaped from the product (EM). Internal exposures are 50-year dose commitments from intakes of radionuclies by inhalation (EN) and by ingestion (ENG) during the specified period of exposure. The total dose to an individual is the sum of the doses received via each of the four exposure modes. This dose is converted (row nine) to a population dose (ED) by multiplying the individual dose by the number of persons so exposed (i.e., by the number of persons in the group being considered (NM) and the probability (EVPROB) that all group members will be so exposed).

Table 1. Components of the life span model and event descriptions assumed for a hypothetical tableware

	Probability of group member being in event	Duration of direct exposure (hr/year)	Effective amount of uranium in source (g)	Distance from source (cm)	Attenuation factor	Duration of immersion (hr/year)	Concentration of uranium in air (g/cm^3)	Duration of inhalation (hr)	Amount of uranium ingested (g)
Transport									
Truck long haul									
Drivers helpers (510)[a]									
Driving	1	28	4,000	650	0.8				
Stops rest	1	8	4,000	9,000	0.6				
Accident cargo fire	.0035					0.08	1.2E-10	0.08	
Persons at stops (5.1E3)									
Normal activities	1	1	4,000	9,000	0.6				
Persons along route (3.57E7)									
Normal activities	1	0.02	4,000	15,250	0.3				
Motorists (3.57E4)									
Passing trucks	1	0.02	4,000	3,050	0.6				
Use									
Commercial use									
Dishwashers (500)									
At work	1	2,000	375	90	1	2,000	8.3E-16	2,000	
Servers waiters (1000)									
At work	1	1,000	500	152.5	1	250	8.3E-16	250	
Patrons (7.5E6)									
Dining out	1	4	500	61	0.9				1.0E-4
Passersby (9.99E7)									
Normal activities	1	0.02	1,000	18,000	0.5				
Disposal									
Landfill									
Collectors (30)									
At work	1	1	100	90	0.7				
Passersby (1.0E5)									
Passing cans	1	0.02	100	150	0.7				
Fill workers (40)									
At work	1	1	500	9,000	0.5				
Area users (1.0E6)									
Normal activities	1	8	500	30,000	0.5				
Emergencies									
Transport accident									
Firemen (5)									
Fighting fire	1	1	50,000	3,050	0.7		1.2E-10	1	
Policemen (2)									
Crowd control	1	1	50,000	7,100	0.7		1.2E-10	1	
Medical team (3)									
First aid	1	0.25	50,000	7,100	0.7		1.2E-10	0.25	

[a] Numbers in ( ) are the assumed number of group members.

The above calculations are repeated for each event in which a group is involved. When all events for a group have been processed, the resultant ED's are summed to give a total group population dose (TGD). Similarly, the TGD's are summed to give substage population doses (TSSD); these are summed to give stage population doses (TSD); and the sum of these is the total population dose for the product (TPD) for the specified period of assessment.

Table 2 is an output sheet of doses calculated for the hypothetical tableware modeled in Table 1. Dose estimates are given for each exposure pathway and for each event. Population doses are given for each event, group, substage, stage, and the product. An estimate is also given of the beta-dose to skin from handling the product (see footnote, Table 2). Other output formats are possible, but Table 2 illustrates the maximum amount of information that can be put in a readable output table.

Table 2. Estimated radiation doses to man from hypothetical tableware under assumed conditions of exposure

Population radiation dose from the distribution, use, and disposal of consumer products containing radioactive materials

Sample problem for condos – hypothetical earthen tableware coated with ceramic glaze containing 100 G of 20-year old natural uranium – hypothetical parameters

	Dose per individual involved (mrem/yr)					Population dose		
	External		Internal					
	Direct	Immersion	Inhalation	Ingestion	Total	Probability	Group dose (man-rem/yr)	Total dose (man-rem/yr)
Transport								
Truck long haul								
Drivers helpers								
(5.100E+02 members)								
Driving	7.88E-02	0.00E-01	0.00E-01	0.00E-01	7.88E-02	1.00E+00	4.02E-02	
Stops rest	8.80E-05	0.00E-01	0.00E-01	0.00E-01	8.80E-05	1.00E+00	4.49E-05	
Accident cargo fire	0.00E-01	7.05E-12	7.25E-03	0.00E-01	7.25E-03	3.50E-03	1.29E-05	
Total dose drivers – helpers								4.02E-02
Persons at stops								
(5.100E+03 members)								
Normal activities	1.10E-05	0.00E-01	0.00E-01	0.00E-01	1.10E-05	1.00E+00	5.61E-05	
Total dose persons at stops								5.61E-05
Persons along route								
(3.570E+07 members)								
Normal activities	3.83E-08	0.00E-01	0.00E-01	0.00E-01	3.83E-08	1.00E+00	1.37E-03	
Total dose persons along route								1.37E-03
Motorists								
(3.570E+04 members)								
Passing trucks	1.92E-06	0.00E-01	0.00E-01	0.00E-01	1.92E-06	1.00E+00	6.84E-05	
Total dose motorists								6.84E-05
Total dose truck long haul								4.17E-02
Total dose transport								4.17E-02
Use								
Commercial use								
Dishwashers								
(5.000E+02 members)								
At work	3.44E+01	1.13E-12	1.26E-03	0.00E-01	3.44E+01	1.00E+00	1.72E+01	
Total dose – dishwashers								1.72E+01
Servers waiters								
(1.000E+03 members)								
At work	7.93E+00	1.42E-13	1.57E-04	0.00E-01	7.93E+00	1.00E+00	7.93E+00	
Total dose servers waiters								7.93E+00
Patrons								
(7.500E+06 members)								
Dining out	1.80E-01	0.00E-01	0.00E-01	3.49 03	1.83E-01	1.00E+00	1.37E+03	
Total dose patrons								1.37E+03
Passersby								
(9.990E+07 members)								
Normal activities	1.15E-08	0.00E-01	0.00E-01	0.00E-01	1.15E-08	1.00E+00	1.15E-03	
Total dose passersby								1.15E-03
Total dose commercial use								1.40E+03
Total dose use								1.40E+03
Disposal								
Landfill								
Collectors								
(3.000E+01 members)								
At work	3.21E-03	0.00E-01	0.00E-01	0.00E-01	3.21E-03	1.00E+00	9.63E-05	
Total dose collectors								9.63E-05
Passersby								
(1.000E+05 members)								
Passing cans	2.31E-05	0.00E-01	0.00E-01	0.00E-01	2.31E-05	1.00E+00	2.31E-03	
Total dose passersby								2.31E-03
Fill workers								
(4.000E+01 members)								
At work	1.15E-06	0.00E-01	0.00E-01	0.00E-01	1.15E-96	1.00E+00	4.59E-08	
Total dose fill workers								4.59E-08
Area users								
(1.000E+06 members)								
Normal activities	8.25E-07	0.00E-01	0.00E-01	0.00E-01	8.25E-07	1.00E+00	8.25E-04	
Total dose area users								8.25E-04
Total dose landfill								3.23E-03
Total dose disposal								3.23E-03
Emergencies								
Transport accident								
Firemen								
(5.000E+00 members)								
Firefighting	1.40E-03	8.81E-11	9.07E-02	0.00E-01	9.21E-02	1.00E+00	4.60E-04	
Total dose firemen								4.60E-04
Policemen								
(2.000E+00 members)								
Crowd control	2.58E-04	8.81E-11	9.07E-02	0.00E-01	9.09E-02	1.00E+00	1.82E-04	
Total dose policemen								1.82E-04
Medical team								
(3.000E+00 members)								
First aid	6.45E-05	2.20E-11	2.27E-02	0.00E-01	2.27E-02	1.00E+00	6.82E-05	
Total dose medical team								6.82E-05
Total dose transport accident								7.10E-04
Total dose emergencies								7.10E-04
Grand total dose								1.40E+03

For skin contact of 1.0 hours the beta dose is 0.5090390E-01 rads

Some features of the CONDOS calculational capability include: (1) calculation of doses to nine body organs; (2) product representation by one of eleven source geometries; and (3) internal dose estimation using radiation dose conversion factors that use either ICRP-2 metabolic models (4) or the Task Group Lung Model and new metabolic models (5) to estimate deposition and retention of radionuclides in body organs.

Applications of the CONDOS methodology include:

1. Assessments of specific products. Potential radiological impacts on man can be evaluated from specific products, such as timepieces containing ^{3}H gas (ref. 6) or ^{3}H or ^{147}Pm paint (ref. 7), spark-gap irradiators containing ^{60}Co for use in oil burners (8), and thorium radiatiors in neutron dosimeters (9).

2. Generic assessments. Radiological impacts can be evaluated for a class of products or for use of a radioactive material in industrial processes, such as recovery and reuse of contaminated scrap metals, which involves many possible, but uncertain, uses of the materials (10-12). By looking at many typical uses and exposure situations, it is possible to obtain a range of likely doses from reuse of the contaminated metals.

3. Sensitivity analyses. Frequently, it is desirable to vary assumed exposure parameters and establish a range of possible doses. Also, critics may disagree with some parameters used and, hopefully, will suggest replacement values. These can be inserted easily into the computerized data file and used to calculate a new set of dose estimates.

4. Compare radionuclides. By changing only a few input cards, it is possible to compare doses from many nuclides under identical conditions. For example, in the assessment of scrap metal from decommissioned nuclear facilities, 26 radionuclides (some were actually a composite of several nuclides in decay chains) were examined to determine, among other things, which might give the highest doses for the various modes and scenarios of exposure (11). Another application is in determining the effect of uncertain contaminants. For example, very small concentrations of ^{232}U might be found in uranium-contaminated metals recovered from gaseous diffusion plants. If present, this minute contaminant could deliver as much as 80 percent of the doses from recovery and reuse of the metals (12).

5. Compare product designs. Suppose that a product has been assessed and the manufacturer wants permission to make a design change (e.g., to delete or add a shield). This can be done quickly and simply by changing the few data cards pertaining to the source (product) description and recalculating the doses.

To summarize, the CONDOS methodology is a versatile tool for evaluating radiation doses to man from a variety of exposure situations. Although designed for evaluating consumer products, CONDOS may be used to evaluate doses from exposures to commercial and industrial products and processes. The methodology gives a prescription for modeling a process or the life span of a product and provides a computer code for using the model to calculate radiation doses.

Much of the work mentioned above involved collaboration between many individuals. Dr. A.N. Tse of the U.S. Nuclear Regulatory Commission provided valuable comments and support during development of CONDOS and during its application. O.W. Burke and F.H. Clark of the Instrumentation and Controls Division and D.C. Kocher of the Health and Safety Research Division of Oak Ridge National Laboratory provided most of the computer programming and participated in development of the overall methodology. The various assessments mentioned were carried out by the cited authors. In addition, a great deal of

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DISCUSSION

MR. GALLAGHER: In nuclear sources and services, what would be the mechanism for a commercial agent to utilize the program?

MR. O'DONNELL: I do not know.

MR. GALLAGHER: It would appear to me, in many respects, the program that is developed might be much more advantageous in terms of the commercial agent trying to develop a product rather than perhaps at the regulatory level.

MR. O'DONNELL: I might point out that the program is of course available publicly or it will be when the later version of it is written. It can be obtained through our reactor shielding information center, which means that you would have a copy of the program, not a machine to run it on. Now for the mechanism for getting it to run, I am not sure how that would work out. The NRC, of course, are the people who sponsored the development of this program and our applications have been for them and I am not sure exactly what mechanism they used. There is an industrial cooperation program but I am not sure if you could do it through that or not.

MR. GALLAGHER: Smoke detectors are a perfect example. Part of the information that you have required concerns who wants effectively to put the smoke detector unit on the market and is exactly the same kind of consideration that you are making here in this CONDOS concept. It would appear to me that, why should the person who is in the commercial sphere effectively have to develop this when the technique is readily available to him. It would certainly keep from writing another letter back with another month's delay just asking the question for the very data that you have it programmed for.

MR. O'DONNELL: Actually, it works the other way. The people go around asking for the data from the manufacturer to be able to do the assessments. One of the things done as part of this was to look at new products coming out that were trying to be exempted. In a couple of the examples I gave, of course, the basic information about the products really has to come from the manufacturer. But the overall method is publically available and anyone can get it. I do not know if that answered your question, but I really cannot answer it, because I do not know all the ramifications.

MR. BAILEY: One of the things that the Task Force was looking at is to figure out how we can get the information on such products as radium-smoke detectors and some other things that contain radium and are very similar, and we think it would make excellent comparison to look at the radium-smoke detectors first at and any new category of products which would be subject to exemption. This explains our interest in the CONDOS methodology.

LICENSING for STATE CONTROL of NARM

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The geographical location of the State of Illinois has resulted in its having its fair share of radiation sources. As in other States, the use of radiation for peaceful purposes is increasing annually, as present-day technology advances. Medicine and industry are not only finding new uses, but are expanding their present uses as well.

In reviewing the State radiation control program, as well as the charge of the Illinois Department of Public Health--to protect the health of the people of Illinois--it was noted that a void existed. Illinois did have a medical and industrial x-ray program. With regard to radioactive materials, the Federal Government was licensing and controlling byproduct, source, and special nuclear materials. However, naturally occurring and accelerator-produced radioactive materials (NARM) were being overlooked, with the exception of a State registration program. The registration program did involve the inspection of facilities with radioactive materials, but such inspections were primarily concerned with general protection and safety measures for patients and personnel in accordance with rudimentary rules and regulations. However, the medical and industrial community had relatively free rein regarding how, or for what purposes, they could use such materials.

Recognizing this gap in the State radiation control program, the State legislature amended the Illinois Radiation Protection Act so that after December 31, 1973, the Department of Public Health was given the responsibility to license the use, manufacture, and distribution of radioactive materials not regulated by the Federal Government (then the U.S. Atomic Energy Commission).

After a major revision of the rules and regulations, in which we more or less adopted the Suggested State Regulations for the Control of Radiation, and after the necessary public hearings, new Rules and Regulations were promulgated in May of 1974.

The next months were devoted to the development of necessary license application forms, mailing of such forms to the "licensees-to-be," and the development of administrative policies and procedures; and the times we asked ourselves "What are we doing?" are too numerous to mention.

In March of 1975, the Department issued its first radioactive material licenses. Needless to say, with the large influx of license applications, it took us a period of time to review and actually issue these licenses. To allow for the uninterruption of the facilities' activities with radioactive material, and yet assure that such facilities were not in violation of the law, letters of authorization were granted to all facilities who were deemed to have "timely" applications.

The majority of the original radioactive material licenses were issued by December of 1976. The licenses were written so that approximately equal numbers of licenses would expire each month.

Although compliance inspections of selected licensees were being conducted, the radioactive material license compliance inspection program was initiated in July of 1976. At that time, initial license inspection procedures had been developed, and selected regional field staff had been oriented and trained to conduct license inspections.

Since that time, we have been attempting to modify and streamline our radioactive material licensing and compliance program to more effectively carry out the responsibilities that have been given to us.

At the present time, we have 305 active specific licenses and 61 active medical general licenses. Last year we received about 30 new applications for specific licenses and 20 new applications for medical general licenses. Of the approximately 300 specific licenses, about 90 include authorization for the use of radium-226 or radon-222 for medical therapy. While a number of these also include authorization for the use of radiopharmaceuticals, there are approximately 80 additional licenses that authorize the use of radioactive materials only for nuclear medicine purposes. The remaining 130 licenses are issued to industrial and educational facilities, including 2 nuclear pharmacies and 8 manufacturers and distributors.

We are presently conducting approximately 190 compliance inspections per year.

As previously mentioned, we are continually working to update and improve the radioactive materials program. Within the past few months, we have been fortunate to be able to have licensee data entered into the computer system. This enables us to obtain a number of different types of profiles pertaining to our licensed facilities. For example, we are able to receive profiles arranged by order of license number, alphabetical listing, by priority, by expiration date, and by date of last inspection - both on a regional basis and on a Statewide basis. The computer also automatically generates the license renewal letters, which aids in saving time.

At the present time our law mandates that radioactive material licenses be renewed annually. It is our opinion that the annual requirement was beneficial for the first few years of the licensing program. It required both the department and the licensed facilities to make at least annual reviews of the facilities' programs. Now that both entities have gained a little more experience, and the majority of the initial problems with facilities' radioactive material programs have been worked out, we find that the annual renewal is not as beneficial as it once was. It is, instead, evolving into less program review and more mere "paperwork" for the facilities as they send in their application for renewal year after year. As could be expected, the annual renewals also take up a lot of Department staff time. In an effort to use our time more efficaciously and reduce unnecessary paperwork for the licensees, and yet at the same time, improve the effectiveness of the licensing program, the legislature is now considering a bill that would amend the Radiation Protection Act to allow the Department to renew licenses at a schedule determined by the State Health Department. If this bill is passed, licenses will be renewed at less frequent intervals and the licensees will be required to submit complete new applications, necessitating an indepth review of their programs by both them and us.

We are also in the process of revising our licensing guide and license application forms, so that they will be similar in nature to the new U.S. Nuclear Regulatory Commission (NRC) licensing guide and associated application forms. We feel that this will not only help in improving the materials program, but will also be helpful to those Illinois licensees who have both an NRC radioactive material license and an Illinois Radioactive Material License. Instead of the licensee being faced with having to deal with two agencies with completely different forms and application procedures, both agencies will have similar forms and procedures, making it much easier for the licensee.

We have noted a number of advantages as we have been involved in licensing naturally occurring and accelerator produced radioactive material:

(1) As mentioned earlier, we have been able to fill the "gap" that previously existed in our ionizing radiation control program. The use of NARM materials is now being more effectively controlled and, we feel we are doing a more comprehensive job in protecting and improving the public health, which is our mandated responsibility.

(2) We find we are able to have much better control over the use of radium-226 for medical purposes. For example, with the concurrence of the Department's Medical Use Advisory Board, the Department has limited the use of radium-226 to the treatment of only malignant diseases. In addition, we have been able to get a better handle on other potentially hazardous situations with regard to the use of radium-226. Also, through the licensing program, many old radium brachytherapy sources have been disposed of, either because the physicians did not use them that much anyway, and it was not worth getting a license to continue to keep them; or, now that radium-226 also had to be licensed, they decided they might as well use cesium or another brachytherapy source. In either case, many radium-226 sources, and in many instances, old radium-226 sources, were taken out of service, and the use of much less hazardous radionuclides in comparison to radium-226, are now being used instead.

As in most States, we still come across unregistered and/or unlicensed sources of radiation. For example, a few months ago, a private physician was found to be storing his radium-226 nasopharyngeal applicator in his locker in the doctor's dressing room in a hospital. The radium, which was stored in an unmarked container, was being used to treat non-malignant diseases, and to the physician's knowledge, had never been leak tested in the 42 years he had possessed the source. So, one does have to admit that just because a State has a NARM licensing program it does not mean there are no problems like the one just mentioned!

(3) We believe that we have been able to aid in improving the quality of instrument calibration and leak test services offered within Illinois. We have also been able to help individual hospitals and facilities improve the quality of their own in-house calibrations and leak test programs. Each radiation survey instrument calibration procedure and leak test procedure is reviewed by the Department prior to the issuance of a radioactive material license.

Prior to Illinois becoming a Licensing State, we did not review leak test or instrument calibration procedures. We were mainly concerned that sources were leak tested and instruments were calibrated.

(4) Through the licensing program we believe that we have also been able to establish a better rapport and a closer working relationship with the radiation facilities. They know us better and we know them better and are able to help each other out and exchange information more freely.

We have also found ourselves more closely associated with the manufacturers and distributors of radioactive material, especially as we are involved in evaluating their products in accordance with the NARM Guides that were developed by the Conference. (By way of interjection, the NARM Guides have been very helpful to us, both as we evaluate various sources, and also as we evaluate leak test kits and services. The whole NARM evaluation concept and associated Radioactive Material Reference Manual, have been very helpful to us.)

As we involve ourselves in evaluating new sources and devices, we find that we can help in assuring the integrity of the sources that are distributed by Illinois firms and have also been able to give advice and assistance to manufacturers to improve their product from a radiation safety standpoint. I remember one case in particular where a manufacturer was able to use a new method to mount the radium-226 source in the product, in such a way that it not only alleviated the potential problem with contamination, but also improved the manufacturing efficiency.

(5) The fact that Illinois is a Licensing State is also an asset to manufacturers and distributors of NARM material. As such, they now have radioactive material licenses from a regulatory authority, which may be recongized by other licensing authorities. This makes it easier for their products to be licensed in other States, since they do have license to distribute the particular product and the product has been evaluated in accordance with the

NARM Guides. A product distributed by a manufacturer in a non-Licensing State must be looked at a little closer by a licensing authority in another State since he is not as well assured of the integrity of the source and its acceptability for licensing.

(6) As I alluded to it earlier, we are, in many ways, attempting to develop our program so that it will be similar to the U.S. Nuclear Regulatory Commission program. Aside from the fact that we are still very new in this area of licensing of radioactive material (and that we can learn a lot from the experience that the NRC has gained over the years), we have two basic reasons for doing this: (a) it is much easier for our licensees, as both the State and Federal licensing agencies will have programs and procedures similar in nature, and (b) if and when we become an Agreement State, it will be a very smooth transition for both the licensees and the Illinois Department of Public Health.

As far as attempting to develop and maintain our program, so that it is consistent with that of the NRC's, Illinois is very fortunate in that the Region III office, which is located in Glen Ellyn, Illinois, was chosen to be a pilot office for NRC licensing on a regional basis. As such they have a very close working relationship with our office, and they have been able to answer many of our questions and help us out many times. It is especially helpful as they also have a close working relationship with many of the same facilities that we license, and we can help each other out in that way as well.

It is obvious that we are "getting our feet wet" and getting valuable experience, which will be very helpful in the event we become an Agreement State. As with everything, there are always disadvantages. There are probably two major disadvantages with becoming a NARM Licensing State.

The first, as you may have guessed, is cost. Everything costs. We charge annual application fees of $50 for users and $100 for manufacturers and distributors, resulting in a revenue of $15,000 per year. However, program costs are approximately $104,000 per year. This, however, calculates out to about $0.01 per capita per year. We are currently spending 4.76 man-years of effort in the licensing program.

The second disadvantage is that there may presently be some duplication of efforts by both the Illinois Department of Public Health and the NRC in one area, namely, in the diagnostic nuclear medicine area. At the current time, the majority of the radiopharmaceuticals used in nuclear medicine are under the licensing jurisdiction of NRC, while there are in comparison relatively few NARM radiopharmaceuticals being used. As a result, the facility's radioactive material program for compliance with NRC requirements automatically includes the NARM radiopharmaceuticals as well. However, any improvements to a facility's radioactive material program that are required as a result of a State of Illinois inspection of the NARM materials, will probably also naturally be implemented by the facility for NRC materials. So I am not sure that we would classify it as a duplication of effort, or whether we should recognize it instead as an advantage, by saying one agency's efforts complement the other's!

In conclusion, we feel that the advantages to the people of Illinois of the Department of Public Health's licensing naturally occurring and accelerator produced radioactive material far outweigh any disadvantages. We believe we can do a better job in fulfilling the responsibilities that have been given to the Health Department.

The experience gained thus far has been very beneficial, we believe, to both the Department and to the licensees. We will continue to try to develop the NARM materials licensing and compliance program, so it will become more effective in accomplishing its intended purpose.

DISCUSSION

MR. KERR: Of the 360 licensees, do you know approximately how many of them also have NRC licenses and do you have a relative comparison of their compliance record with those that do not have NRC licenses.

MR. EASTVOLD: I would say that the majority of the medical facilities, also have NRC licenses. Probably the area in which they would not have both NRC and Illinois licenses would be in the industrial area, especially gauges--where they mainly have radium gauges.

MR. KERR: How do they perform?

MR. EASTVOLD: As far as the number of deficiencies of a non-NRC licensee compared to an NRC licensee I should say that they would probably be equal. It is hard to tell because you are really comparing two different types of facility. The medical facilities mainly have both NRC and Illinois licenses; therefore it is hard to compare. But of the industrial licensees, a lot of them do not necessarily have NRC licenses.

MR. SIMMONS: Do you issue general and specific licenses?

MR. EASTVOLD: We have specific licenses and also medical--general licenses for in vivo and in vitro.

MR. SIMMONS: Do you make concurrent inspections with the NRC?

MR. EASTVOLD: At times we have gone with the NRC, but usually we do not.

MR. SIMMONS: Because you are issuing a license and the NRC is issuing a license to the same licensee, do you get any feedback from the licensee on their attitude toward this dual inspection?

MR. EASTVOLD: Sometimes, as one might expect, licensees are confused about what is under Illinois license jurisdiction and what is under NRC license jurisdiction. They get confused as far as what we are doing and what NRC is doing, but I think generally we have not had a big problem.

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CONCURRENT SESSION E-1: LASERS

Moderator: *Lawrence J. McDonnell*, Wisconsin

USE AND MISUSE OF LASERS IN MEDICAL PRACTICE
Herbert T. Wood, Gregory B. Talley, and Norman J. Stewart, Environmental Health Administration, District of Columbia, Department of Environmental Services

ANOTHER LOOK AT LASER LIGHT SHOWS - BRH ENFORCEMENT ACTIVITY
Robert T. Handren, Consumer-Industrial Products Branch, Division of Compliance, Bureau of Radiological Health, FDA

EVALUATION OF LASER LIGHT SHOW HAZARDS
Jerome E. Dennis, Consumer-Industrial Products Branch, Division of Compliance, Bureau of Radiological Health, FDA
James E. Frye and John J. Galli, Executive Director of Regional Operations,FDA

THE MODEL STATE SAFETY REGULATIONS FOR LASERS
Jack C. Rogers, Consultant, Encino, California

CONCURRENT SESSION E-2: CREDENTIALING

Moderator: *John R. Stanton*, New Hampshire

FEDERAL ACTIVITIES IN OPERATOR CREDENTIALING
Polly C. Story, Division of Training and Medical Applications, Bureau of Radiological Health, FDA

CREDENTIALING: THE "NITTY-GRITTY" OF IMPLEMENTATION
Donald R. Hughes, Radiation Control Branch, Kentucky Department for Human Resources

PROPOSED REGULATIONS FOR QUALIFICATIONS OF LICENSED USERS OF RADIOACTIVE MATERIALS
H. Ellis Simmons, Director, Division of Radiological Health, Nebraska Department of Health

RECOMMENDATIONS OF THE CREDENTIALING TASK FORCE FOR ALLIED HEALTH OPERATORS
Joseph M. Nanus, Chief, Training, Division of Occupational Health and Radiation Control, Texas Department of Health

CONCURRENT SESSION F-1

Moderator: *Eddie S. Fuente*, Mississippi

HOW TO USE THE NARM GUIDES
Edgar D. Bailey, Administrator, Radiation Control Branch, Division of Occupational Health and Radiation Control, Texas Department of Health

LICENSING STATE CONCEPT - HOW IT WOULD BE IMPLEMENTED
Albert J. Hazle, Director, Radiation and Hazardous Waste Control Division, Environmental Health Protection, Colorado Department of Health

THE DISCOVERY AND ASSESSMENT OF FORMER RADIUM PROCESSING SITES
Albert J. Hazle, Director, Radiation and Hazardous Waste Control Division, Environmental Health Protection, Colorado Department of Health

BIOLOGICAL INDICATORS AS AN AID IN DOSE ESTIMATION
Francis J. Bradley, Radiological Health Unit, Division of Safety and Health, New York State Department of Labor
Niel Wald, Graduate School of Public Health, University of Pittsburgh

CONCURRENT SESSION F-2

Moderator: *Ted Wolff*, New Mexico

REPORTING OF ENVIRONMENTAL RADIATION MEASUREMENT DATA
R. Colle, Office of Radiation Measurement, Center for Radiation Research, National Bureau of Standards

OKLAHOMA TLD
Rita S. Patel, Donald J. Burke, and Robert L. Craig, Oklahoma State Department of Health

STUDY OF THE LONG-TERM EFFECTS IN THE BEAGLE FROM WHOLE BODY EXPOSURE TO IONIZING RADIATION-CURRENT FINDINGS
S.A. Benjamin, G.M. Angleton, A.M. Hargis, R.S. Jaenke, A.C. Lee, C.W. Miller, R.W. Norrdin, and R.D. Phemister, Collaborative Radiological Health Laboratory, College of Veterinary Medicine and Biomedical Sciences, Colorado State University

PLENARY SESSION

Moderator: *Alice Dolezal*, Minnesota

IS THERE AN ENVIRONMENTAL RADIOFREQUENCY RADIATION PROBLEM:
David E. Janes, Office of Radiation Programs, EPA

FDA'S PROPOSED PROTECTIVE ACTION GUIDES FOR FOOD, MILK, AND THYROID-BLOCKING
Bernard Shleien, Office of Health Affairs, Bureau of Radiological Health, FDA

THE "TRUTH" ABOUT THREE MILE ISLAND, HARRISBURG, PENNSYLVANIA AND THE IMPACT ON RADIATION PROTECTION AGENCIES
Panelists:
Thomas M. Gerusky, Director, Bureau of Radiation Protection, Pennsylvania Department of Environmental Resources
Robert G. Ryan, Director, Office of State Programs, Nuclear Regulatory Commission
Bernard Shleien, Assistant Director for Scientific Affairs, Office of Health Affairs, Bureau of Radiological Health, FDA
Floyd L. Galpin, Director, Environmental Analysis Division, Office of Radiation Programs, EPA

CLOSING
David Lacker, Chairman, CRCPD, Texas Department of Health
Robertson J. Augustine, Director of Operations, Office of Radiation Programs, EPA
Sheldon A. Schwartz, Assistant Director for Program Development, Office of State Programs, Nuclear Regulatory Commission
James W. Miller, Assistant Director for Dentistry, Office of Health Affairs Bureau of Radiological Health, FDA

USE and MISUSE of LASERS in MEDICAL PRACTICE

Herbert T. Wood, Ph.D.
Gregory B. Talley
Norma J. Stewart

Bureau of Occupational and Institutional Hygiene
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District of Columbia
Department of Environmental Services

Lasers are used as medical devices in three applications in the District of Columbia. These are:

1. As alignment devices for linear accelerators,
2. For treatment of diseases of the eye, and
3. For treatment of diseases of the cervix and vagina.

Each of these applications uses a different type of laser.

Lasers are used as alignment devices for linear accelerator applications at two hospitals in the District of Columbia. In each case the lasers are mounted in the wall and ceiling with only the aperture showing. Two lasers are mounted in the walls and one in the ceiling. All three beams meet at one point. In each case the lasers were Model 904 helium-lasers manufactured by the Virian Corporation. The rated output was 10 mW at 632.8 nanometers.

The lasers were controlled by a single switch located on the wall by one of the apertures.

In neither case were the lasers labelled, warning signs posted, or precautions taken during the use of the lasers. There was no indication, other than the spot on the walls and floor that the lasers were on.

Two hospitals in the District of Columbia are involved in the use of lasers for treatment of problems involving the eye, including retinal welding and cauterization of blood vessels on the retina. In both cases, the lasers in use are argon lasers manufactured by the Coherent Radiation Corporation. The radiation consists of a green line at 514.5 nanometers and a blue line at 488.0 nanometers. The output was smoothly controllable up to 5 watts. The spot size could be varied from 0.05 to 1.0 millimeters.

The apparatus consisted of a desk console which contained the power supply, the laser, and the cooling water system.

The laser light is transmitted by a fiber optics system in a flexible arm to the working end of the unit. This is a fixture to hold the patient's head (a chin plate and a forehead strap), a binocular microscope for the doctor to examine the retina of the patients' eye, and a shutter arrangement to keep the laser beam contained until the aiming is completed. A foot pedal activates the shutter allowing the beam to enter the patient's eye. At the same time, the shutter closes the optical path of the binocular system to prevent radiation from entering the eye of the physician. Aiming of the beam is accomplished by an arrangement where a small portion of the beam, severely attenuated, enters the eye with the shutter closed.

In both hospitals the lasers are used in rooms that were available, not designed, for their use. Each room contained many surfaces capable of specular reflection and the output end of the device was capable of orientation in any direction. Neither door had an interlock.

At one hospital the room adjoining the laser room was an office. The door leading to the laser room had a laser caution sign on it. At the other hospital the room was incredibly small (less than 7 feet across) and opened into a reception area. There was no sign on the door indicating the use of lasers nor were there any interlocks. According to rumor, patients were brought into the room in beds, which necessitated leaving the door open during procedures.

Neither laser was labelled in any way.

The third laser procedure being performed in the Distric of Columbia involves the use of a carbon dioxide laser manufactured by Laser, Incorporated. The laser is used to destroy abnormal cells on the vagina and cervix. Its output is in the infrared region of the spectrum (10,600 nanometers), has a beam diameter of 2 mm at 1 meter, and can be smoothly adjusted up to 25 watts. A console contains the electronics, a tank of carbon dioxide, a cooling system, and necessary controls. This unit is capable of timed or continuous operation using a hooded foot pedal.

The laser itself is attached to a side arm of a pedestal mount. A shutter arrangement prevents the beam from leaving the laser until a hooded foot pedal is depressed. Because the radiation is not visible, a mark in the optical system allows the physician, using a binocular system similar to the argon laser described above, to aim the beam. Since long wavelength infrared is generated by this laser it will not penetrate glass. Thus, the shutter system is such that the optical path by which the physician aims the beam is not closed when the beam is on. When the beam is on, a visual signal (a red light) is activated on the console.

The laser is used in a normal operating room. Everyone in the room is required to wear dark glasses during the procedures. The room, of course, is full of surfaces capable of specular reflections, and there are no sights or interlocks on the door. A safety procedure sheet is available, however.

It is obvious from this investigation that the lasers used for medical devices are being misused. Minimum precautions such as the use of warning signs and labels are not being used. In particular the aperture label, as required for medical devices, was not present in any case. None of the lasers had the manufacturer-supplied procedure and schedule for calibration as required by the Radiation Control Act. In two cases, the physician stated the manufacturer checks the lasers annually.

More importantly, in all three hospitals the radiation safety officer stated that lasers were not his responsibility. Thus, the degree of care with which the laser is handled is left entirely up to the physician. In only two cases was any effort at all taken to provide for safe use of the laser, and these efforts were inadequate.

Based on this investigation the following recommendations are made: (1) That the Conferences' Task Force No. 10 on Nonionizing Radiation develop a handbook of recommended practices for the use of medical lasers; (2) that the Conference make the recommendation that medical lasers become the responsibility of the hospital radiation safety officers; and (3) that the inspection of lasers used for medical devices be made part of the States' annual licensure inspection of hospitals.

ANOTHER LOOK at LASER LIGHT SHOWS - BRH ENFORCEMENT ACTIVITY

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Last year at Harrisburg, a discussion on laser light shows was presented. This paper presents an update on the Bureau of Radiological Health's activities in this area, but first, a brief review of the problem. When the Federal Laser Product Performance Standard was being developed, an attempt was made to address the potential entertainment and demonstration laser product market. The regulations, which finally became effective on August 2, 1976, effectively limit demonstration and entertainment laser products to Class II levels of accessible laser radiation. In the visible range this provides an effective power limit of 1 mW of laser radiation. By early to mid-1977 it became apparent to the Bureau of Radiological Health that there was a growing use of lasers in the music, entertainment, and advertising industries. In particular, musical groups and discotheque operators were using lasers to create visual effects designed to compliment the music being played. Lasers were also being used for visual effects in theaters, planetariums, and various advertising media. The systems used to generate these visual effects were asembled using general purpose Class III or IV laser systems in most instances and consequently exceeded the 1 mW limitation already present in the regulations. Before the Bureau could actively attempt to regulate this industry it had to be determined that such manufacturers were in fact subject to Public Law 90-602 and the regulations promulgated to enforce it.

The Food and Drug Administration's office of the General Counsel determined that individuals who engage in the business of performing laser light shows and of commercially selling such effects and devices perform an act of manufacture under the law and therefore such individuals are subject to all of the regulations promulgated to enforce the Radiation Control for Health and Safety Act. Further discussions between the Bureau and the Office of the General Counsel indicated that the act of physically assembling such a device at each particular location could also be considered an act of manufacture. Also, it was almost a virtual certainty that some modifications or changes would be necessitated during a relatively short period of time (adding effects, redesigning projectors, and so forth) and those modifications that would also constitute additional acts of manufacture thereby making virtually all projectors subject to the laser performance standard.

On November 23, 1977, the Bureau issued Policy Statement No. 22, which announced to the laser industry that the Bureau did in fact have jurisdiction over this type of manufacture and that all such systems introduced into commerce must comply with the Federal Performance Standard. If this was not possible or desirable, the manufacturer must have a variance from that standard. A second Policy Statement (No. 23) was issued on February 21, 1978. In that statement the Bureau indicated that if certain safety criteria were followed, and a report on the laser product and a variance application were submitted, the Bureau would refrain from enforcement of that section of the standard, which limited power to 1 mW. This policy would apply only when the information submitted was adequate to describe the product, and the variance application provided enough supporting documentation to allow the Bureau to make the assumption that such a show would be operated in a safe manner. It was also required that the Bureau have the opportunity to inspect the show at a time convenient to the Bureau. This approach was necessary because the facts of life relative to the laser light show industry are that in many cases very little or no time elapses between a request for a laser light show and the actual time that it must be presented. It would therefore be virtually impossible to process a variance and have it published to cover a single performance. Our current approach to the variance problem is to suggest that manufacturers request a "generic" variance, which would allow any or all of the types of shows to be performed. The basis of such a variance would be the safety criteria discussed below and in our February 21, 1978 policy statement.

The Food and Drug Administration will and has taken appropriate enforcement action to prevent the assembly, introduction into commerce, and continued operation of laser light shows or displays that fail to meet the above conditions. The following are the laser safety criteria imposed by the Bureau for Class III and IV laser light shows and displays.

1. Laser radiation emission outside the visible wavelengths (400 to 710 nanometers) must not exceed the emission limits of Class I under any possible conditions of operation.

2. Laser and collateral radiation measured where the audience is normally located must not exceed the limits of Class I during operation. Radiation to be measured includes reflections from targets and scattering materials.

3. Operators, performers, and employees must be able to perform their functions without the need for exposure to laser and collateral radiation in excess of the limits of Class I if such radiation is intended to be viewed or in excess of the limits of Class II if such radiation is not intended to be viewed.

4. Scanning devices, including mirror balls, must incorporate a scanning safeguard to prevent laser emission if scan failure or other failure causing a change in either scan velocity or amplitude would result in a violation of the preceding two criteria.

5. If the laser light show does not operate at all times under the direct supervision or control of an operator, radiation levels to which "human access" (21 CFR 1040.10(b)(12)) can be gained must not exceed the limits for Class II at any point less than 6 meters above any surface upon which a person in the audience is permitted to stand or at any point less than 2-1/2 meters in lateral separation from any position where a person in the audience is permitted during the performance or display.

6. Laser light shows or displays that do not meet criteria 5 shall be operated at all times under the direct supervision or control of a trained operator who shall maintain constant surveillance of the laser display and terminate emission of laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions. Laser radiation levels to which "human access" can be gained must not exceed the limits of Class II at any point less than 3 meters above any surface upon which the audience is permitted to stand or 2-1/2 meters in lateral separation from any position where a person in the audience is permitted to be unless physical barriers obstruct access by the audience to such levels.

7. All laser light shows or displays must be provided with one or more readily accessible controls to effect immediate termination of laser radiation. If the light show or display is not required to be under the continuous supervision or control of an operator during its operation there must be a person at all times at the show or display who is designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions.

8. The maximum output power above Class II shall be limited to that required to perform the intended function of the product.

9. The laser light show or display must meet any other radiation safety criteria that the Bureau of Radiological Health believes is necessary to adequately protect public health and safety. In addition, the laser operator and or laser safety offi-

cer responsible for producing a laser light show should contact the local or State radiation control officials or health department prior to a show to determine that any applicable local or State requirements are satisfied and clearance is obtained before the show or display goes on. Additionally, for laser light shows that project high power beams into the atmosphere, appropriate FAA clearance must be obtained. We originally stated that these notifications should preferably be done in writing. Current experience indicates that such notifications should or must be made in writing and we are currently requiring this of all manufacturers.

Examples of some of the additional requirements that BRH has imposed under criteria 9 are: when Class IV beams are to be terminated upon some material, this material must either be provided or sufficiently evaluated by the manufacturer to ensure that there is no reflection or fire hazard; when a single operator does not have visual access to all areas potentially exposed to laser radiation, secondary operators with either laser termination devices or direct communication with the principal operator have been required; and, the use of guards or additional barriers have been required in some instances.

Laser light shows typically fall into several categories, the first being laser light shows associated with fixed installations. Examples of such fixed installations would be planetariums, discotheques, amusement parks, fixed art displays, and certain types of advertising displays. Planetariums using lasers are now relatively common and trade names such as "Laserium" are used. Discotheques such as New York, New York, and Xenon in New York City, Circus Disco in Milwaukee, and many others are currently using or considering laser lighting effects to accompany their music. Amusement parks have also been installing laser light shows similar to the "Laserium" type to attract additional customers. Art displays such as the one still in operation at the Omni in Atlanta, Georgia, although relatively uncommon, are of sufficient number to be considered as significant. Advertising applications of laser light are currently not very popular, however, the technology for producing advertisements using lasers which write on clouds or the side of a large building is available, and the Bureau has in fact been approached by several manufacturers who desire to use this type of advertising medium.

The other major breakdown for types of laser light shows would be the mobile installations. These mobile installations typically involve music groups who use laser projectors to give dramatic visual effects concurrent with the rock music. Examples of groups who have used or are using laser light shows are the Blue Oyster Cult, KISS, Paul McCartney and Wings, the Electric Light Orchestra, Genesis, the Bee Gees, Led Zeppelin, Pink Floyd, Soleil, and so forth. Other forms of mucical concerts have also used laser projectors such as the "Star Wars" type of concert where the lasers are used to produce visual effects similar to those seen in the movies as laser weaponry. Another form of mobile shows that are becoming more popular involve the use of an inflatable dome shaped building in which a laser projector is centered. The audience then lies on the floor gazing at the ceiling while various effects similar to those in planetariums are produced.

Currently, 48 out of 270 laser product manufacturers, are known to be active in the laser light show business; 35 have reported to the Bureau, 29 have applied for a variance and 33 manufacturers have been inspected by the Food and Drug Administration with a total of 126 inspections. It has been estimated by Bureau personnel that if all of the currently active laser light show manufacturers and the potential laser light show manufacturers were added, it would approximately double the total number of companies with which the Bureau does business. Given the large potential audience appeal for the different types of laser light shows indicated above and the fact that any individual who purchases a general purpose visible laser system has at their disposal a device capable of producing spectacular lighting effects, it becomes obvious that the potential for laser light shows is extremely large. It is also apparent that the use of Class III and IV lasers in an unsafe manner could have a severe impact on public health and safety. This potential has had a great effect on the actions of the Bureau during the past year and a half and has resulted in a significant expenditure of resources in an attempt to get a handle on this situation. Unfortunately, this is not an easy task to undertake. It would be extremely simple to merely enforce that section of the laser standard that limits laser demonstration products to Class II levels of accessible laser radiation. However, this approach would totally ignore the historical fact that the use of lasers for demonstration purposes has not resulted in injuries because the lasers were operated in a mature and professional manner. On this basis the Bureau felt it was necessary to take the positon that as long as a manufacturer demonstrated the desire and capability to perform laser light shows in a safe manner, BRH would not interfere.

To date the Bureau has initiated regulatory action against several laser light show manufacturers. Only one of these actions has come close to involving a court case. In that case the individual involved signed a consent decree, has paid a $1,000 fine, has agreed to bring all applicable products into compliance, and has agreed to pay for the FDA inspections of the repaired products. In addition, several declarations of noncompliance and regulatory letters have been issued to manufacturers. All of these have resulted in either compliance with all BRH requirements or, at the very least, significant changes in the manner in which the laser light shows were produced and operated.

Examples of some of the conditions observed during inspections that resulted in these declarations of noncompliance and issuance of regulatory letters included direct scanning of audiences with laser radiation in excess of Class I limits, laser projectors that had grossly inadequate protective housings allowing access to high levels of collateral and scattered laser radiation, faulty setup procedures that permitted hazardous exposure to laser radiation of various employees either connected or not connected with the laser light show, unsafe conditions that permitted excessive exposure of performers to laser radiation, inadequate equipment design, such as lack of scan failure safeguards, and so forth.

As to the future, it appears that as the technology of laser light shows becomes more sophisticated, the number of actual manufacturers may be decreasing. We will always be faced with the problem of individuals doing unusual things, but the majority of manufacturers seem to be developing into buisiness ventures based on sound principles and procedures. In a word, most are becoming more professional in their approach. Those who do not, can expect that legal actions will be initiated against them as required by the regulations.

Current indications are that discotheque installations will increase greatly during the next year while road shows will remain essentially constant and "one-shot" exhibitions will drop in number. It is hoped that the laser light show situation will become more manageable as these trends continue.

In closing, it is hoped this information will be of use to you all. Laser light shows are becoming widespread and constitute a significant part of the laser industry. BRH can't possibly cover all those current or potential installations, we need the assistance of the States. We are attempting to develop a procedure that will provide information such as touring group itineraries, laser equipment and use description, and so forth, to any State or local authority who desires it. There are mutual needs, which if acted upon could reduce everyone's anxiety over these shows.

EVALUATION of LASER LIGHT SHOW HAZARDS

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INTRODUCTION

In this discussion we will present some suggestions for steps that can be taken to assess the hazards and safety status of laser light shows without having to make measurements. Mr. Handren covered some of the types of shows that have been proliferating and the requirements that have been imposed upon the producers of such shows. We shall now consider those checks that you can perform in forming a decision about what action if any to take in a show situation.

ADMINISTRATIVE CONTROLS

As Mr. Handren has said, producers of laser light shows are considered to be manufacturers of products subject to the Radiation Control for Health and Safety Act of 1968. As such, they are required to have certified that their products comply with the applicable standards and to have documented that compliance in a report to the Bureau of Radiological Health. If the products exceed the limits of the standard for demonstration laser products, which is almost always the case for commercial laser light shows, there must also have been a submission of a variance application. The Bureau has been refraining from initiating enforcement while approval of the variance is pending. In those cases where the required reports and applications have been submitted, the FDA would have sent the submitter acknowledgments that assign reference accession and docket numbers. You can reasonably expect the light show producer to know these numbers, and quite often they will carry copies of acknowledgments with them on tour as evidence of having complied with their requirements for reporting and variance application. We have also seen cases where the producers have carried copies of the submissions themselves. In assessing the value of reference numbers and acknowledgments, bear in mind that you are dealing with individuals who are quite creative. The value of such evidence is only that the producer has made some submissions. You cannot be sure that the submissions are adequate or that the show will comply with the safety measures contained in the submissions as a result of environmental factors (such as seating locations or other architectural features). Nor can you be sure that the show will not contain new effects that were not included in the submissions, or, at worst, that the submissions covered an altogether different show by the same producer.

Included in the Laser Light Show Safety Criteria distributed to the industry by BRH is an instruction to contact local or State radiation control officials. Ideally, such contact should have been made in writing and the producer should have a copy of such communication. Examine any such correspondence to determine whether the show plans any deviations from the notification. If contact was made by phone, determine when and with whom the contact was made. For sky shows that is, effects that use scattering in the atmosphere or reflections from clouds, evidence of FAA notification should also be sought.

If you have any doubts or questions about whether the show producer has reported and applied for the variance, you can call the Light Products Section, Division of Compliance, BRH at (301) 443-4874. We will be happy to tell you whatever we can about the producer and the show.

INSPECTIONAL ASPECTS

SAFETY DOCUMENTATION

As BRH has been moving towards developing standardized safety conditions for approved variances, we have recognized the value of safety documentation of laser light shows. We consider documentation showing that adequate safety procedures have been followed essential for favorable consideration of a variance application.

The following types of documentation are considered essential and should be maintained by the light show producer or operator:

1. a listing of the laser lighting effects to be used during the show;
2. a description of each effect, including assessments of audience exposures for each effect;
3. descriptions of how the effects are utilized in context of the entire show;
4. assembly and checkout procedures, including a checklist for verifying proper operation of all safety circuits, and checks for compliance with safety guidelines; and
5. planning and evaluation drawings of the specific show in the facility showing locations of projectors, components, effecs, and audience.

Without actually taking measurements a physical inspection can be made of a number of aspects of the show and the projection equipment.

Determine the total power output of the show. Ask the producer about this and ask how this level was determined.

Check by witnessing checkout tests that this maximum level is consistent with the audience exposures given in the description. Is the level to be used the maximum power capability of the projector or is the projector operated at reduced power? If the projector is to be operated at reduced power, what assurances can you obtain that the power will not be increased during the show to permit higher than allowable exposures?

Does the producer have the ability to measure the output? If so, what are the results of such measurements and have the results been recorded in the checkout log?

A physical inspection can be made of the projection equipment to include the following items. Does the projector have adequate protective housings or beam enclosures to prevent access to all but the necessary outputs? Are the projectors mounted in a stable manner so that they cannot move causing beams to be projected in unintended directions? Also check external components such as mirrors for stability of mounting. Determine whether there are means to prevent performers or audience from entering into high level laser radiation areas or disturbing the placement or alignment of any components; more will be said of this later.

The use of baffles on projectors or enclosures is often appropriate to prevent either electrical deflection or movement of a component from directing a beam in an unintended direction. Check whether any such baffles are present and if so, that they have been properly set for the particular show and the fact of baffle setting has been entered in the log. To do this check, you can ask the operator to position the stationary spot to its maximum deflection in each direction and then apply a scanning signal. If the beams travel too far in any direction to satisfy the safety criteria, baffling of the projector would be needed.

The laser projector can also be inspected for required labeling. There should at least be warning DANGER logotype, laser aperture, and certification/identification labels. Be aware that many laser light show projectors incorporate certified laser systems and that it is necessary for the projector to be independently certified.

Class III and IV projectors must also incorporate a key switch, beam attenuator (shutter), emission indicator (with emission delay), and connector for optional interlock or safety switch.

SHOW CONTROL

Even if the documentary control and equipment appear to be in excellent order, potentially dangerous conditions can exist if the show is not properly controlled. The following are items to evaluate in assessing the physical control of the show environment.

Determine the means to be employed in keeping the public far enough away from Class III or Class IV laser radiation fields to satisfy the BRH safety criteria. Will there be physical barriers, fences or roped off areas? Will warning signs be posted? Warning signs do not necessarily contribute to safety; they may attract the curious to enter area that otherwise might not have been of interest. Will guards, police or attendants be posted with specific instructions to keep the public out of designated laser radiation areas and have they been instructed on what to do if people do enter that area?

Determine who are the responsible individuals. These would include the show's road manager and producer, laser operator, and the facility's security director and manager. Each of these key persons should know each other and where each will be stationed during the show. A chain of communication should be established. Agreement should be reached on what action will be taken and by whom in case a hazardous situation occurs. It has been our experience that facility managers can be very effective in persuading producers to delete certain effects from a show if the manager has been advised by a radiation control official that a particular effect constitutes a public health hazard. Generally, managers are sensitive to liability that might be incurred if an accident occurs and they have ignored such advice.

EFFECTS AND SAFETY CONSIDERATIONS

Several lighting devices and effects that we have observed will be discussed with emphasis on the unique safety considerations of each. We hope that these will provide some additional insights that will help in your assessments of shows that you might encounter.

Audience Location

Make sure before a show that all key personnel know and agree where the audience will be permitted and where laser effects are to be projected.

Mirrors, Windows, and Lighting Fixtures

In making a physical inspection of the facility put yourself at the locations of any projectors and look for any reflective surfaces such as mirrors, windows or lighting fixtures that are within your field of view. Specular reflections from such surfaces can range from 5 to 90 percent of the incident power. Reflective surfaces are likely to be encountered on spotlight or movie projection booths, scoreboards, advertising signs, and spotlight lenses. Make sure that laser radiation will not be directed to hit such targets so that reflections that could exceed the limits of the BRH safety criteria could be directed into the audience. If such would be the case, the targets should be removed or covered with a diffuse material.

Audience Irradiation

The BRH safety criteria dictate that audience irradiation may not exceed Class I limits. If irradiation of the audience is included in a show either directly or by specular reflection, it would be necessary to confirm that the limits of the safety criteria are not exceeded. This is best done by analysis knowing the maximum power, scanning parameters, and geometry. Measurements of other than direct stationary beams are extremely difficult to make, require much complex equipment, and are difficult to defend. You should reasonably, expect the producer of the show to be able to produce his analysis and can readily check that the maximum power and geometry of the actual show are consistent with that analysis.

Mirror Balls

In addition to mirror balls that are integral parts of some laser light shows, mirror balls are not uncommonly found in theaters, arenas, and discotheques. Unless the mirror balls are a part of the shows they should be considered in the same category as mirrors, windows, and lighting fixtures discussed earlier. In general, laser radiation must be scanned on a mirror ball in order to comply with the BRH safety criteria. Consider also that if a laser beam hits a flat mirror on the bottom of the mirror ball, the plane of the mirror would be perpendicular to the axis of rotation so that rotation of the mirror ball would not scan the reflection from this particular mirror. As one progresses up the ball towards the equator, the radii and speeds of the reflected spot increases. Near the lower pole the radius and linear velocity of the reflected beam are minimum so that it is often necessary to have the lower portion of the ball blackened or covered with a diffuse material. We have encountered one arrangement in a theater where mirror balls were placed behind blocking screens to permit only reflections that would fall on a diffuse projection screen.

Front and Rear Projection Screens

Projection screens should be checked for holes or open seams and for stability of mounting. Make sure that the projected displays will not overfill screens causing laser radiation to reach unintended areas. Reflections and transmissions from fabric and plastic screens are usually Class I by the time they reach the audience. Problems may be encountered with beaded or metalized screens. If rear screen projection is to be used, make sure the back stage projection area is secure.

Scanning Safeguards

The BRH safety criteria require that there be a scanning safeguard that operates to prevent audience exposure to greater than the limits of the criteria in the event of scanner failure. This requirement applies not only to the scanners on the projector but also to mirror balls. A scanning safeguard operates by optical or electrical detection of the motion of the scanning optical element and usually operates a solenoid shutter to block the laser radiation if the scanning signal is not present at the required rate. It is not difficult to verify electrical connection of scanning safeguards. Verification of proper operation of the scanning safeguard should be a routine part of the checkout procedure and noted in the log. There should be no difficulty imposed in asking to see proper operation of the scanning safeguard demonstrated to you.

Dwells

We have noted in some cases emission of unscanned beams between effects in a basically scanned show or before a scanning safeguard operated to terminate the radiation. This is a less than desireable condition. In general and especially in high power shows, scanning safeguards should be able to terminate laser radiation before scan failure would be visually detected. Also, shutters should usually block the laser radiation between effects and numbers. In those cases where a beam dwell must occur, verify that the position of dwell will not result in a hazardous situation occurring.

Deflection Overshoot

During an inspection we noted that during setup procedures for a show, the laser operator used the deflection controls on the projector to make sure that the beams would impact only on the projection screen. Baffles were adjusted as needed to prevent the beams from missing the screen if the scanners could be driven to cause enough deflection to do so. During the dynamic operating conditions of the show it was noted that where baffles were earlier not thought to be needed, the scanners could be driven to greater peak deflection than possible under static conditions. As a result some of the laser radiation overshot the screen. Fortunately, a hazardous condition did not result in this case. You should be aware of this type of potential hazard. Diffraction and diffusion effects also leave the projector with larger divergences than possible for scanned radiation. Projector baffles should be used in both axes. In retrospect, for the example cited, the baffles should have been set to the position of maximum static deflection even though they did not appear to be needed during setting up.

Audience Items

Unexpected hazardous items may be brought to a show by the audience. We are aware of helium-filled metalized polyesther balloons and metalized "Frizbees." We believe that there will be laser light shows at many State fairs this coming season and would be surprised if metalized balloons were not sold at all of them; the balloons are a very popular item. We have also become aware of audiences at rock concerts throwing bottles, cans and even pyrotechnics at each other and at performers. In addition to the hazards posed by the projectiles themselves, laser radiation hazards could also result. It might be possible for you to have sales of potentially hazardous items restricted.

Last Minute Setup

Almost invaribly, delays occur that prevent accomplishment of detailed meticulous inspections. We have personally experienced having to keep thousands of people at the gates of an amphitheater while trying to complete our work. As can be imagined such delays or the cancellation of a show can create more significant hazards of other sorts. In coping with this difficulty we would advise early completion of your physical assessment of the facility and coordination of key personnel. As show time approaches it will be increasingly difficult to accomplish these tasks.

We believe that setups and alignments should be done at the lowest possible powers and should protect workers installing other equipment. If time does not permit the following of established setup and safety procedures, we do not think those parts of the show should go on.

CONCLUSION

The ideas that have been presented should not be considered as hard fixed rules. Neither can they be expected to be applicable or work in all situations. They may help you in planning your light show inspections and actions. To close on an optimistic note, we have found most of the major firms in the laser light show business to be serious and sincerely interested in putting on safe shows. They realize as well as we do that if injuries do occur and become known that their livelihood will be in serious jeopardy. In most cases if you ask for modifications or deletions of effects you can expect cooperation.

The MODEL STATE SAFETY REGULATIONS for LASERS

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Late in 1971, the Conference of Radiation Control Program Directors foresaw the need to consider recommending Suggested State Regulations for Lasers (SSRL) for uniform adoption by States. This was occasioned by requests from States who were finding increased use of lasers without effective controls. The committee originally consisted of F.J. Bradley, New York; Willian Bryan, Colorado; Joseph F. Thiel, Texas; and Jack C. Rogers, California. Following Mr. Bryan's retirement he asked to be dropped from the committee.

The Committee's task was to develop a conceptual draft for the Conference to accept and submit to the States for their consideration as the requlatory requirements on laser usage. Because of the interest of other agencies (Federal and other) in this issue, contact was maintained with all agencies such as OSHA, NIOSH, FDA-Bureau of Radiological Health, ANSI Committee Z136.1, as well as individuals and interested organizations.

Early in 1974 an initial draft was prepared for review. During this period of time the Electronics Products Division, Bureau of Radiological Health under the authority of the Electronics Products Bill, developed an Industry Committee (TEPRSSC) to review the Bureaus' Regulatory requirements on laser "product" manufacture. Because of the overlap of requirements in specific areas such as the classification, tables, and so forth, your committee held activity in abeyance pending the results of the TEPRSCC Committee and BRH action on the Performance Standards for Laser Products, 21 CFR Part 1040, which became effective August 2, 1976.

We finalized a Draft of SSRL in 1976 for review by agencies and selected States who were currently enforcing Laser Regulations. The comments received, and they were voluminous, were reviewed and a committee meeting of almost a week of intensive discussion incorporated the comments into a revised draft. Every report received was commented on for response back to the reviewer. Charles P. Froom, Division of Compliance, Bureau of Radiological Health and his staff provided our committee with the assistance to document and redraft all of the items considered for change. This became the August 1976 draft.

On February 1978 a final draft was submitted to the Conference Chairman, Dale McHard, including the rationale and the analysis of all comments on the preliminary review. The draft SSRL has had hard scrutiny by all concerned Federal agencies, the ANSI Committee, and selected States and is compatible with the FDA Performance Standard for Laser Products. This draft, dated April 1978, was then given much wider distribution for comment.

What does the document provide? Is it just another level of bureaucracy on a selected industry? The Committee feels that standardization of regulation is important. The SSRL will provide this to the States as well as Federal agencies, such as OSHA, who may be considering Laser Regulations. The Committee was just the medium for pulling together and digesting all comments into a workable draft. The misuse of lasers in "laser shows" has created a serious atmosphere within States for some rational control of laser uses. This issue is addressed in Appendix B of the proposed SSRL. There is no question that hazardous levels of exposure associated with laser uses in the future should and will be regulated. I feel it is important that we be rational in what really requires regulation. Incidentally, the Bureau has recently received an Attorney General's ruling that lasers used in a light show are "laser products" and as such come under the purview of 21 CFR 1040 enforced by the Bureau.

The SSRL addresses this issue by eliminating the required registration of lasers, which by definition are identified either as Class I or Class II. The SSRL supplements the Federal Standards, which address only the manufacture of the products, whereas the SSRL addresses the question of safe use of lasers and the user. The proposed SSRL is compatible with existing recognized standards and regulations. In addition information was provided in this single document, by including an appendix on Medical Surveillance taken from the ANSI Z-136.1 document. Timing of the Committee's activity limited us originally to consideration of the ANSI 1976 adopted standard. Obviously updating may be necessary if the changes are significant.

The SSRL is codified in four parts. Part A covers General Provisions including definitions; Part B covers provisions for registration of Class III and Class IV lasers; Part C covers the laser radiation protection provisions, safety, eyewear, signs, labels, and posting. Because the existing eye examining procedure has been under some controversy the Medical Surveillance Procedure was listed as an Appendix for information purposes.

The Committee was aware of other hazards associated with laser useage, such as, ionizing radiation, air contaminants, electrical fire, and cryogenic hazard; however these hazards are not addressed in these regulations as it was felt that other existing regulations cover these issues.

The rationale accompanying the SSRL provides further clarifying information on the reasons for the individual provisions. The consideration of States' Rights made it necessary to have optional wording in certain provisions such as registration. However the basic provisions of the SSRL would remain uniform.

I feel that I can express the feeling of the Committee that documenting the proposed SSRL will tend toward uniformity without sacrifice to health and safety. States have already moved toward individual considerations of laser regulations. We hope that uniformity will provide for easier compliance nationwide. The Committee has already received more than 50 comments on the 1978 distribution of SSRL. These have all been reviewed and codified. At a meeting of our committee held January 1979, the committee met jointly with representatives of the ANSI committee and the Electronic Industries Association. There was much discussion on why do we need any further regulation. We have an ANSI Standard, BRH has a product requirement, industry has had a safe record and could regulate itself. After much discussion way into the night, the consensus was that perhaps the suggested regulations have a role for user safety. The ANSI Standards, which are recommendations only, are apparently undergoing another revision. Drafts of these changes are being made available to our committee and will be incorporated into our 1979 Final Draft. Hopefully all comments will be responded to and the final draft submitted to the Conference Executive Committee for distribution by early summer. The final version of SSRL therefore will be updated to the 1979 ANSI Standards and compatible with other Laser Safety Standards and written as a regulatory document for consideration for adoption by States and local agencies.

FEDERAL ACTIVITIES in OPERATOR CREDENTIALING

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(The author declined to submit a manuscript for publication. The following is a transcript of the presentation made at the Conference with minor grammatical changes. We regret the inconvenience this may cause the reader.)

I am going to be very brief this morning. In no way could I begin to tell you in 15 minutes, Federal Activities in Operator Credentialing; so what I want to do is to just touch on a few of the subjects to make you aware of them and then to have a few minutes for questions at the end.

First of all what are we speaking of when we speak of credentialing? I think credentialing can be defined as the formal recognition of technical or professional competence. Normally, there are two routes to gain that recognition. One is certification and the other licensure, which of course is the one that is of more importance to you State Radiation Control Program Directors.

Certification is a process by which a nongovernmental agency grants recognition to one for their professional or technical competence after that individual has met certain predetermined qualifications. In licensure, it is recognition granted by the State with the purpose to protect the public health.

Who are we speaking of when we speak of operators? Somewhere out there, there are between 130,000 and 170,000 operators of medical diagnostic x-ray equipment. Additionally, you have between 12,000 and 14,000 individuals working in nuclear medicine and better than 2,000 in radiation therapy. Of that number, approximately 80,000 are credentialed; i.e., certified or licensed. That leaves between 50,000 and 90,000 individuals operating x-ray equipment who have never demonstrated, by a measurable tool, their competence in the the performance of examinations. Of course this matter is of interest to the Bureau, because the purpose of the Bureau is to reduce unnecessary radiation exposure; and in allied health medical radiation exposure and to optimize the necessary exposure.

To touch on a few of the things that have gone on at the Federal level, there is a Bill that has been introduced into this U.S. Congress by Senator Jennings Randolph, S-500. This is really nothing new because there have been similar bills introduced in the last five Congresses. To date, none of them have passed. S-500 is somewhat different: previous bills mandated State licensure, S-500 encourages State licensure. Basically, it is designed after a Presidential Document that came out in January of 1978. I do not have time to touch on the details of S-500 but if there is anyone who wants to review the Bill, please feel free to do so after we get through with our session.

I mentioned the Presidential Document on Radiation Protection Guidance to Federal Agencies for Diagnostic X Rays. This is a document that was signed by President Carter after recommendations were made by EPA and by HEW. There are 12 recommendations in this document. Recommendation No. 8 addresses operator qualifications. It states that operators of equipment should demonstrate competency equivalent to or greater than that of recognized credentialing agencies. There is a Task Force, or a Subcommittee I guess you would say, that is addressing Recommendation 8. It has representatives from FDA, EPA, the VA, and the Department of Defense. The Subcommittee is looking at uniform qualifications for those individuals who work in Federal facilities.

Another subject in credentialing at the National level, this little booklet, Credentialing Health Manpower. This document has six recommendations. Of great significance I think, is particularly Recommendation No. 2. Two of the recommendations, 3 and 4, address State licensure. They state that before a State embarks on a licensure program, it should examine the situation very closely. Recommendation No. 4 states that for those States that have State licensure, their programs should be improved. Recommendation No. 5 has to do with competency measurements. Recommendation No. 6 has to do with continuing education along with the competency measurements in Recommendation No. 5.

Recommendation No. 1 suggests that there be a National nongovernmental agency to, in essence, certify the certifying agencies. In December of 1977, the National Commission for Health Certifying Agencies had its Constitutional Convention in Miami, Florida. So Recommendation No. 1 has come to fruition.

Recommendation No. 2 reads: "National Standards for the Credentialling of Selected Health Occupations should be developed and continually evaluated. Professional organizations, other elements in the private sector, and State governments should play a significant role in this process. The Standards thus developed should be utilized for the various purposes for which standards are required, including Professional Certification, Licensure, Private Sector and Civil Service Employment, and Third Party Reimbursement."

Recommendation 2, National Standards: the Secretary of HEW has directed FDA through the Bureau of Radiological Health to develop recommendations for National Standards for Qualifications of Medical Radiation Technologists. As such, on March 13, there was printed in the FEDERAL REGISTER, a Notice of Intent. I hope that every one has received this. We invite your comments, your rationale, any data that you may find fitting to share with us.

On the National scene there are basically two examinations for examining competency of individuals. The most widely known is that of the voluntary sector of the American Registry of Radiologic Technologists. Additionally, there is an examination for the testing of proficiency of x-ray technologists that was developed by ETS under contract to HRA. In some of the States, those States that have enacted or enabling legislation, the State programs are having difficulty in getting tests to administer. In September, the States approached the Educational Testing Services, willing to use the National ETS Proficiency Exam. Several meetings were held, as a result there is now a multi-State Licensing Advisory Committee. They are meeting with ETS to determine the feasibility and the desirability of using the ETS exam as a National exam, really a mini-national exam for those States that have State licensing.

In the area of credentialing, the Bureau has been a contributor to the Conference Task Force. And I believe Joe Nanus is going to tell us about that. Although it does not actually participate in State licensure, the Bureau does assist those States with programs or those who have enabling programs upon request. I just wanted to bring you up to date on the States that have State licensing. Currently, there are nine: Arizona, California, Hawaii, Kentucky, Montana, New Jersey, New York, Oregon, and West Virginia, in addition to the Province of Puerto Rico. Six States have enabling legislation: Deleware, Florida, Georgia, Michigan, Minnesota, and Vermont. Additionally, two States, California and New Jersey, have authority to regulate the user or the operators of nuclear medicine equipment.

CREDENTIALING: The "NITTY-GRITTY" of IMPLEMENTATION

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In a February 27, 1979, Department of Health, Education, and Welfare press release, Secretary Califano stated that the Food and Drug Administration will expand and expedite its current program for setting specific guidelines for the education, certification,and testing of x-ray, nuclear medicine, and therapy technicians. This commitment is certainly gratifying because up until now, all States have been addressing the credentialing of radiation operators on an individual basis. It is hoped the action taken by the Department of Health, Education, and Welfare will have a consolidating effect regarding credentialing nationwide. Approximately 20 percent of the States either conduct ongoing credentialing programs or have enabling legislation providing for the establishment of such programs. A great amount of time, effort, and money has been spent assuring that x-ray equipment meet minimum safety standards, and it is imperative that the issue of radiation operator qualifications also be addressed.

Various bills for the credentialing of radiation operators have been before Congress for the past decade. This year is no exception, and I have been told by some sources in Washington that passage of the current credentialing bill, Senate Bill 500, stands an even 50/50 chance.

I do not want to stand here and discuss the pros and cons of Senate Bill 500. That is not yet a reality; however, what I would like to do is to pose a hypothetical situation. Let us suppose Senate Bill 500 became law today. I would like for each Radiation Control Program Director in this room to think about the imapact that passage of that Bill would have on their State. Senate Bill 500 provides a period of 2 years, whereby States can implement their own law. If, by chance, some of the States have not done so by that time, then those States would be forced to adopt a credentialing program that would be formulated by the Federal Government. I would hope the expertise that is available in various States conducting credentialing programs would be used, should a Federal law ever be drafted.

In recent weeks the press went wild and the perennial candidates for high office got on their soap boxes at Pennsylvania's Three Mile Island exercise in how to lose friends and influence no one. The pathetic result of that exercise in reactor mismanagement was that the actual release of radioactivity at the site was an infinitesimal speck when compared to the large amount of radiation that medicine subjects the general population to on a daily basis. You know and I know that with the exception of radiologists, physicians receive very little training, if any, in the area of radiation protection. Most physicians with any practice at all will delegate the responsibility of producing a diagnostic quality radiograph to their trusted radiation operator. In more than 50 percent of the time this person, laughlingly called a radiation operator, has not had any formal training and has only been exposed to the teachings of the general practitioner, which definitely leaves something to be desired.

Five or six years ago, when the Federal moratorium was in effect, the State of Kentucky decided that something must be done about the untrained radiation operators who were needlessly subjecting patients to unnecessary amounts of radiation. At that time, we not only went against the Federal moratorium, but we were opposed by the healing arts professions and even the 2-year trained radiological technologists. Perhaps you can now begin to appreciate the words "Nitty-Gritty" in the title.

Years and years of collecting data and performing radiation safety inspections on thousands of x-ray machines, clearly showed that by ignoring the operators of that x-ray equipment, we were only looking at half of the problem. How would a State go about starting its own credentialing program if it were opposed by the medical profession and qualified radiation operators? The answer to that question is very simple--you educate the general public.

Medical costs are constantly increasing. When the general public finds out they are possibly being subjected to substandard care by individuals that have never been formally trained in radiologic technology, they will demand quality care by competent radiation operators.

Credentialing by itself will accomplish nothing; however, credentialing can be an excellent tool when properly used. In the name of credentialing, you will be able to establish schools and approve curricula to be used for teaching radiation operators. In the name of credentialing, you will be able to test those individuals currently employed as radiation operators but lack any formal training. Also, in the name of credentialing, you will be able to require some form of demonstrated proficiency or continued education prior to the credential renewal process. Once the general public is made aware of the situation, the medical community or any group for that matter, cannot afford to express any opposition to formal training of radiation operators.

At this point in time, I would encourage each State to take a long, hard look at what type of credentialing program would best suit them. If you plan to include various professions in your credentialing program, then you will need different types of certificates. Some professions are highly specialized and limit their practice to certain parts of the anatomy, while others are given carte blanche privileges with the whole body. This obviously implies different types of training. Worded another way, not all professions are the same, and should not be treated the same.

You may want to consider multiple credentials within the same profession. Medicine, for example, contains numerous specialities and their radiographic projections may range from an occasional chest to a highly complicated special procedure in the operating room.

Let us consider training. If you decide to use multiple credentials, where will the various training come from? There are several choices. you might wish to recognize and make use of the already existing AMA approved schools for radiologic technologists. You could always create and establish your own school for each type of credential or you could recognize and approve the use of correspondence courses such as those produced by the University of California at Berkley. The choice is yours, but I would suggest that any educational program be a joint effort between yourselves and your own State department of education.

Grandfathering! If you should start a credentialing program, do you recognize everyone currently employed as a radiation operator or do you administer an examination, which may be written, practical, oral, or any combination of the three? If you do not administer some form of testing, then you will have to explain why you are continuing to allow untrained radiation operators to perform radiographic examinations. After all, that was one of the reasons why you would want to implement a credentialing program.

Money! The fee system is an important consideration. Will the taxpayers foot the bill since they are the intended recipients, or will each radiation operator be required to pay for something they probably did not want in the first place. Worded another way, can your program solely exist on fees collected or will you be allowed to appropriate monies from the general fund.

Competency! How do you improve the quality of the various radiation operators? Improvement in the curriculum and the quality of the instructor will upgrade future radiation operators. For those untrained radiation operators who are currently employed, some form of proficiency evaluation must be initiated. Proficiency evaluation may be accomplished by several methods such as retesting, on site evaluation, or supervisory assessment. Another method to improve the quality of the radiation operators would be to require a certain amount of continuing education prior to the renewal of credentials. Any State that is conducting or plans to implement a credentialing program would be foolish to do so without incorporating some mechanism for assuring continued competency prior to credential renewal.

Advice! State programs designed to credential radiation operators are relatively new. You will be offered advice from all professional organizations whether that advice is solicited or not. Each State should establish a credentialing advisory committee but should avoid appointments that would place any one profession in the majority role, and membership on the Committee should be representative of all professional organizations involved with credentialing.

In conclusion, there is no single approach to credentialing. Each State is an entity unto itself, and a credentialing program must be tailored to fit the demands of existing conditions. However, particular attention should be given to reciprocity to assure the mobility of radiation operators between States. I hope the Conference will approve the report submitted by Task Force No. 5 and make it available as a guidance mechanism for establishing a State credentialing program for diagnostic radiation operators.

DISCUSSION

MR. NEUWEG: Don, I think, has a method to get to the public to start our credentialing program. Since you have put in this time do you have any data to show that the credentialing system has helped in your State or does it appear too early to judge?

MR HARDIN: At the present time we do not have but are collecting data in that respect. The exact questions you have asked of trying to compare, for example, the reduction in collimation, and the use of other protective devices in the practice of radiology. But frankly we have not had the time to really see the impact of true credentialing. The actual requirement that everyone be credentialed throughout the State has a final date of June 30, 1979. So you can still see the beginning of our program is not even really moving.

MR. NEUWEG: I know in our State we tried for 2 or 3 years and I have personally always been concerned with the effect, and if there are some other States here that are represented that do have programs or have had for a few years, if they have some good concrete data to show that the program is effective, I think this would be very valuable to the rest of us.

MR. HARDIN: I fully agree. I think what you are asking is that we in the credentialing area have some real hard facts. I personally have made many inspections where I know the conviction could help. As an example, in a facility which was a medical-indudstrial type facility I asked the technologist who was not a certified technologist nor a registered technologist, to let me look at the technique chart. And she said, "I have no technique chart." "Well, where is it? How do you decide your exposure parameters?" And she simply said, "I put the patient up there, I set the knobs, press the button, go develop the film. If it looks good, fine, if it does not, we go back and try it again and reset the knobs."

That was a true situation I experienced personally and I suspect that it happens more than once throughout the United States. But that sort of situation of retaking is the ultimate extreme and I fully support the need for hard facts, hard data. I know that is what the Bureau is looking for and I think that we credentialing States need to try to start bringing this material together.

MS. STORY: I believe Mr. Hardin said that a State had 2 years to adopt the standards. If the States failed to adopt new standards the Federal standards would become the standards of that State. That was the provision in old 1695, and HR-4573 and the ones in the previous bills. I believe that in this one the Federal standards do not become the standards of the

State because there is no mandatory mechanism there and instead the funds for eligibility pursuant to that particular section was terminated.

MR. HARDIN: As I indicated when I started, I am not that familiar with the details of the standard. If that is correct Polly, I am delighted to hear that to know that the requirement is not placed on us.

PROPOSED REGULATIONS for QUALIFICATIONS of LICENSED USERS of RADIOACTIVE MATERIALS

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It may be of interest to some of you as to how we came to draft the qualifications for licensed users of radioactive material as regulations. In 1966, the original regulations without these qualifications were adopted and approved. Subsequently, the regulations were revised completely in 1974.

The State Attorney General's Office on reviewing all of the State Regulations at this time gave an opinion that the Department of Health, Radiological Health Regulations went beyond the intent of the legislation or the Radiation Control Act. They concluded that we could license radioactive sources but not people.

Needless to say, this upset me greatly, especially when I discovered that certain sections of the Radiological Health Regulations relating to licensing had been already deleted. This left us without much authority to licensing anything.

This seemed to bother the Nuclear Regulatory Commission a little bit, too. To make a long story short, we had the legislature change the wording of the Radiation Control Act and drafted new Regulations.

In doing this we ran into some problems, we were using a draft copy of the proposed Regulations, which had not officially been approved, and a final edition proved that some things had been changed, which certainly makes secretaries happy. To make certain we did things right, we conferred with the Attorney General's office to determine what was legal and what would be acceptable. During one of these conferences, one of the Attorney General lawyers indicated we should by regulations detail the qualifications of the user to be licensed to use radioactive material.

It was her opinion that any license issued required certain qualifications of training and experience to possess that license. Our intelligent arguments were: the Nuclear Regulatory Commission does not do it; no other State is doing it. In addition, this is a new and rapidly changing field, which requires highly qualified individuals (health physicists) to make the decisions on who should be qualified to use radioactive material. If we set rigid qualifications for training and experience it will require constant regulation updating to remain current with the state-of-the-art.

The Attorney General retorted, your decision can be arbitrary and capricious and you should not be the judge on qualifications on who can and who cannot be licensed to use radioactive material without specifying these qualifications by regulation.

I now submit to you those Regulations which provide the qualifications required for the licensed user to possess and use radioactive material in Nebraska, providing our new Regulations pass the final test of approval by the Attorney General's office and the Governor.

It was really not too difficult to draft these requirements, as many of you know, the Nuclear Regulatory Commission and the Agreement States have for years been using guidelines to direct their review of license applications to appropriately assess the qualifications of the user. We reviewed these guidelines, modified them and finally drafted these guidelines as Regulations.

In some instances guidelines were not available. In this case the staff and myself developed those training and experience requirements we considered adequate for specific licensed radioactive material.

We have had few objections on the training and experience and requirements for the licensed user as regulations. We feel that it has helped us in our Department in that it eliminates those arbitrary and capricious decisions made by the employees. It has definitely helped our program when we send out the guides on making a license application, and the applicant can quickly review whether he is qualified to use the material in question.

I have listed the individual licensed users for which we have established qualifications by regulation. You may not agree on what we have established. We do not know how reasonable they are, but they may be useful to some of you as guides. The following use categories have been established by regulation. They appear to cover all our current licenses. In addition, we have included the qualification and training for human use or particle accelerators.

Medical Human Use

Group I, Schedule C (uptake, dilution, excretion)
Group II, III, Schedule C (diagnostic imaging)
Group IV, V, Schedule C (therapeutic uses)
Group VI, Schedule C (sealed sources, brachytherapy)
Teletherapy

Education, Research Manufacturing, Industry, etc.

Industrial Radiography
Institutional Broad Scope, A, B, and C.
Educational Institution license other than Broad Scope.
Licenses to manufacture and introduce radioactive material into manufactured products and devices.
License to introduce radioactive material into radiopharmaceuticals.

Industrial Licenses - Well logging and others

Industrial licenses
Irradiator personnel
Industrial gauges
Gas chromatograph
Particle accelerators - human use

I do not feel it is necessary for me to review what we are using for the qualifications of the licensed user. I have copies of these available, and if additional copies are needed I will send you one.

DISCUSSION

MR. TEDFORD: I think there are several elements really in the implementation of certification or licensing and this has been most interesting to me in my short tenure in Georgia. These several elements are not only the public but the legislature, the medical profession, and all the ingredients that go into casting a law if you will. At the present time in Georgia we have a bill introduced into our legislature which would require licensing by various technicians groups. It has never cleared out of committee. And how I hear the mention of the Attorney General and the fact that we do have the right to set rules, requirements, and to upgrade. The training, the background, and the efficacy of people who work in the program is our question. I mentioned this to my Medical Advisory Committee when I first came to the State and it was close to heresy at the time because we had not had any program there. We recently had a BENT program but suprisingly enough, the Medical Advisory Committee was very open to this suggestion. The point I want to make is this: That it is a naive approach to say that just the public is going to influence this. It is a legislative process, it is a medical profession process, and it is a process that I feel is mandated by the requirement and the necessity that specific Federal guidelines come out in this area which can be seen as precedents and all States should go in that direction.

MR. BENSON: I was curious about the inclusion of accelerator operators. Did you consider taking that one further step to include all operators of electronics products that emit radiation, particularly of course, x-ray machines.

MR. SIMMONS: No. We had enough trouble doing what we are doing and I think we need to see how it works out. I definitely thought we needed it with particle accelerators. As you know they are moving completely away from cobalt teletherapy and going to particle accelerators for treatment and there is no qualification or anything. Generally they are the same people, but we thought we would put it in and it passed, and I think it is a step in the right direction. We are going to see how it goes with this and then we may add it for other users.

RECOMMENDATIONS of the CREDENTIALING TASK FORCE for ALLIED HEALTH OPERATORS

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It was 1976. The Conference was meeting in Springfield, and Workshop No. 8 on "State Credentialing Program for Radiation Allied Health Operators" made a recommendation to the Conference that a task force be appointed on the credentialing of operators using sources of ionizing radiation.

These 16 people recognized the need for operators of sources of ionizing radiation in the allied health professions to be uniformly proficient in the performance of their duties. The National Conference of Radiation Control Program Directors, based on that recommendation, established a task force to study the needs of a credentialing program.

The first year charge to this Task Force (No. 5) was to develop recommendations on design of a credentialing system for radiation operators. Specifically, the objectives of Task Force No. 5 were to determine purposes, goals, and relationships in a credentialing system and define its options; to evaluate the advantages and problems related to existing and proposed credentialing activities; to identify the occupational groups that should be included in the credentialing system; and to propose a framework for a credentialing system.

This task force was active throughout the year gathering information from the Bureau of Radiological Health, numerous States, resource persons, and professional organizations. This information, in the form of questions and answers relevant to credentialing, was primarily utilized as a basis for the development of their first report given at Seattle by Don Hughes, Chariman.

Don reported that it was the unanimous conclusion of the task force that MINIMUM NATIONAL STANDARDS should be established for the credentialing of individuals operating sources of ionizing radiation in the allied health professions and that credentialing programs shall be State administered and controlled. The task force also determined that available evidence has shown that credentialing, in some form, has resulted in improved job performance and reduced patient exposure. The problem, as they saw it, was how does one credentialing system provide a mechanism for all States to guarantee that all allied health radiation operators are at least equally competent at some level? Minimum credentialing standards universally applied would assure that this competency level is achieved and maintained.

The occupational groups identified and the order of their priority for credentialing was determined by the task force based on the amount of exposure they apply to the consumer public:

1. Diagnostic Radiologic Technologists/radiation operators
2. Nuclear Medicine Technologists/technicians
3. Radiation Therapy Technolgists/technicians

As previously stated the task force determined most emphatically that credentialing programs shall be State administered and controlled; therefore, the Conference, because of its structure, would be the natural promulgating body for such a minimum standard.

The major functions of the credentialing task force as charged by the Executive Committee were:

(a) Recommend to the Conference, for approval, Minimum Credentialing Standards and Implementation Guidelines and make available all necessary information to support these recommendations.

(b) Assist States in the development of credentialing programs.

(c) Obtain data from States to assist in the evaluation of credentialing programs with special emphasis on patient dose reduction.

The members of the task force generated a list of 56 questions that were forwarded to each member of the task force for review and response. From this internal survey the task force concluded that a credentialing system shall be mandatory; that it should be controlled and administered by the States; and that the Conference should be the promulgating body responsible for the development and approval of the credentialing system, with minimum standards to be established for all States to use.

They also recommend that an "ongoing task force" should be charged with the responsibility of coordinating all data and make recommendations to the Conference on minimum credentialing standards; that an advisory committee to the ongoing task force should be convened to aid the task force in developing standards, and that guidelines should be established to aid in the implementation of these minimum credentialing standards.

The ideal of an advisory committee to the ongoing task force was rejected by the Executive Committee, but the ongoing task force used an "informal" advisory committee. The results of the input from this informal committee were helpful in arriving at the proposed minimum standard.

Work of the task force has been centered around enlisting opinions from members of the informal advisory committee who are members of organizations that the institution of minimum credentialing standards will affect.

The groups contacted were:

Bureau of Radiological Health,
American College of Radiology,
American Registry of Radiologic Technologists,
American Society of Radiological Technologists,
American Registry of Clinical Radiography Technologists,
Joint Review Committee on Education in Radiologic Technology, and
Health Physics Society.

A number of questions were addressed to these groups through their representatives.

Acting on the recommendations of the previous task force, members of the "ongoing" task force determined to take the information received from the affected organizations and establish statements about the essential components of minimum credentialing. These essential components, identified by the task force the previous year, are:

A. Definitions
B. Basic entry requirements
C. Types of credentials (e.g., general; limited; special; temporary; hardship)
D. Exemptions
E. Renewal requirements
F. Enforcement mechanisms
G. Performance evaluation
H. Fees

I. Administrative mechanisms
J. Reciprocity
K. Testing and/or evaluation procedures
L. Ethical code of conduct
M. School accreditation
N. Challenge procedures
O. Continuing education

The task force then took the conceptual framework from the previous task force and developed statements of intent. Then began the lengthy process to fill in the specific verbage. Progress made included getting more input from several potentially affected organizations, i.e., dental, chiropractic, and podiatric associations.

By the time we reported to the Executive Committee of the Conference in May 1978 on our activities, the members of the task force had agreed to prepare the standards in a modular fashion, writing the present document, a minimum standard for diagnostic radiologic technologists, in a way that such other disciplines, such as nuclear medicine technology and radiation therapy technology, can be added later. The task force has indicated where they envision the place of these other disciplines will be in the overall fabric of what will eventually become an umbrella document on a minimum standard for credentialing of all allied health radiation operators.

We have separated some items of an administrative nature from the standard. These items, which include fees, administrative procedures, school standards for accreditation, and transitional provisions (i.e., grandfathering and the like) are to be part of an implementation document. The members of the task force decided the implementation document will also contain suggested wording for the enabling legislation or statute.

The task force does recognize that licensed practitioners other than those specializing in the use of radiation have a general lack of knowledge of radiation protection and proper radiation use. This, however, was not part of the charge, and we have not considered it, and will not consider it, unless asked to do so by the Conference.

Sometime in the future the Conference will need to consider a mechanism to assist States in their review of programs for determining reciprocity.

Seventeen comment letters were received on the draft sent out in December 1978, and all comments were considered in arriving at the content of the current proposed document, submitted to the Executive Committee last month. One general area of confusion in the comment letters was confusion of regulation and implementation with the minimum standard. In writing this proposed standard, the task force has deviated from all the documents available for review during our deliberations. Whenever possible, mechanics and enforcement procedures and any other items of an administrative nature have been avoided in the standard. For those of you who received the draft of December 27, 1978, the DRT Limited Credential was restructured because the concensus was that there is more than one acceptable way for such credentialing, including incorporation of a career ladder. The standard is broad enough at this point for individual States to meet their own needs though reciprocity may be a problem in this area.

Several comments were received asking how the task force proposed for a part of the standard to be made operational. The task force recognizes that a standard that cannot be enforced is worthless, but it has not been our intention to suggest administrative and enforcement mechanisms in the standard.

The members of the task force have recommended that the proposed standard be adopted by the Conference. They further recommend that the Conference use this document as part of its comments on the Food and Drug Administration's call for comments on their intent to develop recommendations for qualifications of medical radiation technologists, (in FR Vol. 44, No. 50 - Tuesday, March 13, 1979, pp. 14637 - 14738).

Contents of the standard include, definitions, types of credentials, minimum eligibility requirements for examination, exemptions, issuance of credentials (initial and renewal), enforcement mechanisms, reciprocity, testing and/or evaluation procedures, and school accreditation. "Definitions" is pretty self-explanatory.

The Type of Credentials listed include:

1. DRT General - issued to a person, other than a licensed practitioner to apply x radiation to any part of the human body, under supervision of a licensed practitioner.

2. DRT Limited Credential - issued to a person, other than a licensed practitioner to apply x radiation to specific parts of the human body.

3. DRT Dental Credential - issued to a person to apply x radiation to head and neck under the supervision of a licensed dentist.

4. DRT Temporary Credential - issued to allow trained persons to practice while awaiting examination and is valid only until the results of the examination are known.

5. DRT Conditional (Hardship) Credential is intended to be a certificate issued by the Agency to a person when the Agency, with the Health Systems Agency, finds there is substantial evidence that the people, in the particular location of the State where the conditional credential is sought, would be denied adequate health care because of the unavailability of appropriately credentialed persons under this standard. We envision that such conditional credentials shall be granted for limited periods of time, to be prescribed by the Agency, in accordance with the purposes of this standard. A DRT Conditional Credential shall convey only those rights specified in the certificate and we expect the certificate would contain ongoing training requirements. Such temporary credentials may be renewed for cause.

Minimum eligibility requirements for application for credentialing include graduation from high school or its equivalent; attainment of 18 years of age; and freedom from physical or mental impairment which would interfere with performance of duties or otherwise constitute a hazard to the health or safety of patients. Also included are submission of a satisfactorily completed application on a form supplied by the Agency; payment of designated fees; eligibility for examination for the specific credential requested; and such other requirements as may be required by the Agency.

Eligibility requirements for examination are spelled out. DRT General requires completion of an approved program (i.e., school) covering all areas of competence, including radiation protection, technique and quality control, patient care, positioning, equipment and maintenance, special techniques, and clinical experience. DRT Limited requirements are generally the same as DRT General but this may be through an approved course of study, which may or may not be in a school.

The task force recognized that the extent of knowledge necessary for the DRT Limited Credential is dependent upon the specific credential requested, and will be less comprehensive than the extent of knowledge required for the DRT General Credential. The DRT Limited category was written in this manner to provide the appropriate State Agency latitude in the development of the limited credentialing system.

Exemptions are provided for students enrolled in and participating in an approved program or approved course of study for radiologic technology or an approved school of medicine, osteopathy, podiatry, dentistry, chiropractic, dental hygiene, and dental assistance, who as a part of their course of study apply ionizing radiation to a human being while under the supervision of a licensed practitioner. Licensed practititioners are also exempted, in line with the charge of the task force.

An exemption for Federal employees was discussed but, since this is a minimum standard, they should be included. It is recognized, however, that when the standard is implemented by a State, the State may have no jurisdiction in Federal facilities.

Initial issuance of the appropriate credential should be made to the applicant who passes the examination or is otherwise qualified (e.g., reciprocity).

Frequency and mechanism for renewal of credentials should be established by regulation or statute. It should require submission of evidence of completion of the required number of continuing education credits/hours, or proficiency evaluation, (e.g., retesting, onsite evaluation, supervisory assessment, and so forth.

Renewal of conditional credentials should require an onsite visit for proficiency evaluation in addition to normal renewal requirements. The Conditional certificate may also specify certain training requirements to be completed prior to renewal.

Please note, the task force feels strongly that credentialing by a government agency of persons who apply ionizing radiation to humans can only be justified on the basis of public health. The Agency must assume the responsibility for good radiologic technology practice, acting as an advocate of public health. No standard should be enacted unless it contains a method of reducing nonproductive radiation exposure to the patient/consumer.

Enforcement mechanisms are addressed in the standard, only to the extent that a statement is made that enforcement is not part of the standard, but part of the implementation document.

Reciprocity will become practical only if based on a nationally accepted standard. In the interim there will be a one-to-one reciprocity between States. Every effort should be made for new States addressing the issue of credentialing to adopt this standard to promote reciprocity.

The expertise of existing national voluntary credentialing organizations is recognized and is referred to in the standard in its statement on reciprocity.

On the subject of testing and/or evaluation procedures, the task force feels that a uniform national test should be given for different levels of credentialing. A nationally uniform pass point should be used. An example of a proficiency test that might be considered is the test developed by Education Testing Service, Princeton, New Jersey, under contract with the Division of Associated Health Professions, U.S. Department of Health, Education, and Welfare. National voluntary credentialing organizations have tests developed, but at this time they are not available for use by State credentialing bodies.

When discussing school accreditation, the task force determined that the credentialing agency should consider the accreditation, approval, or certification of the school by other agencies or organizations when approving schools for instruction to prepare the student to demonstrate minimum eligibility requirements. This can be done if the Agency determines that the accreditation, approval, or certification was granted on the basis of standards equivalent to those of the certifying agency. In addition, consideration should be given to cooperation with nationally recognized accrediting agencies and those recognized by the U.S. Office of Education.

In conclusion let me offer two additional items concerning mechanics.

1. It is my understanding that the American Registry of Radiologic Technologists will now make its test available to the State for their testing and evaluation

program. They will allow the persons seeking credentialing to sit for the test and will provide the results to the State which can set its own pass point.

2. The Executive Committee has approved the basic minimum standard. It is contemplated that the standard will be published in the Conference Newsletter, and copies will be supplied to the members of the informal advisory committee. We also want to make it available to the State Technologist Societies through the good office of the American Society of Radiologic Technologists.

If you would like a copy of the standard prior to its publication in the Newsletter, I will be happy to arrange for single copies if you will write me.

DISCUSSION

MR. WHATELY: Were you planning to approve RT's rather than the State test or should the State have a separate test. The State should have a separate test from voluntary credential agencies.

MR. NANUS: We did not make that determination. We said in our section under reciprocity that it would be possible for the State agency to determine whether or not they wanted to recognize other voluntary credentialing agencies.

MR. STEIN: Well, when you develop a test that allows reciprocity, it should be a uniform test at least throughout the whole country so that everybody is being tested on the same thing and the only test other than the NRC that I know of is the one at Princeton which is the Level III, for entry level RT's only. As far as I know they have not developed a test for any others, or a test as to its validity. And for that particular test they propose charging about $75 per test which is expensive to give a test for a State license based on that. That would only be for entrance level x-ray technicians, for general purpose. And as far as I know there is no other test developed and it is difficult for States to develop them on their own and then allow reciprocity because I am sure there would be 50 different tests for each category of license. What bothers me is the cost involved in trying to establish a uniform test which you cannot lose track of security-wise unless some control agency like at Princeton would administer the test and control the actual administration and grading the test. Do you know anything about any other tests that have been developed?

MR. NANUS: I am not aware of any test with regard to, for instance the thing we were talking about under limited credentials. There are some other tests, for instance, the ARCRT has career laddering tests which they use, which are a series of 10 tests that test the various 10 areas they have defined in radiotechnology. But those are not really geared for this and something would need to be developed.

MR. STEIN: We only have the authority in Delaware for radiation protection and not to get into education or any other job-limiting requirements. Based on current practice, radiation safety is the only concern that the Office of Radiation Safety has. They felt that the test should be limited to radiation safety rather than getting into all the rest of it. People who want to hire RT's will do so.

MR. NANUS: My response to that would be that I cannot argue with your law but part of radiation technology is getting the correct exposure the first time. And if the RT's do not know how to position the patients correctly or how to set the technique factors then that is poor radiation protection.

MR. HARDIN: Polly Story is correct in that respect that standards would be placed upon a State if they did not adopt certification. What it does and what would be of interest to the States is that if this Senate Bill 500 is passed then the Secretary of HEW or at least the

Federal agencies would offer up to 50 percent of the total cost for implementing a program in certification either in the licensing procedure or in the establishment of a credentialing-training institution. The States would generally have 2 years in which to get the program going to be eligible for that funding.

HOW to USE the NARM GUIDES

Edgar D. Bailey

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There is a trite old adage that says "if all else fails, read the instruction manual." In the area of evaluating products containing naturally occurring and accelerator-produced radioactive materials (NARM), the "instruction manual" is "Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)" (1). The document is commonly referred to as the "NARM Guides."

Reportedly, there are some State radiation control program directors who have not read the "instruction manual" for NARM products since the Executive Board of the Conference of Radiation Control Program Directors (CRCPD) requested that a paper be presented at this meeting on how to use the NARM Guides. The following is a step-by-step recipe for State radiation control program directors on how to use the NARM Guides.

STEP 1

Obtain a copy of the NARM Guides. Each State was sent at least two copies (one loose leaf and one bound), but since these may have become worn out through constant use you may need to obtain a new copy. Since the NARM Guides were distributed by the Bureau of Radiological Health (BRH), the person to request a replacement copy from is your Regional Radiological Health Representative. (If you already have a usable copy of the NARM Guides, you may skip Step 1 and go directly to Step 2.)

STEP 2

Once you have a copy of the NARM Guides in your hands, open it up, and read ALL (yes, ALL) of the Introductory NARM Guide. After you have completed the laborious task of reading these eight pages, read over two or three of the numbered NARM Guides to get their flavor.

STEP 2a

Take a coffee break. You deserve it after having completed Step 2. However, if you have an insatiable appetite for hard work, you may proceed directly to Step 3.

STEP 3

Contemplate which of the three NARM product options you want to use to evaluate NARM products that are manufactured, assembled, or distributed by companies located in your State.

OPTION 1: The State radiation control program does the entire review and evaluation.

OPTION 2: The State radiation control program asks the BRH to do the entire review and evaluation. (Remember that the State program in this option still has an obligation to be a go-between between the company and the BRH.)

OPTION 3: The State and the BRH cooperatively perform the review and evaluation. The State does as much of the evaluation as it wants to do. The BRH does only that portion that the State wants it to do.

Once you have considered these evaluation options in light of your program's available staff and time, make a decision! Choose the option that is best for your program.

STEP 4

Having selected the evaluation option you wish to use, have a member of your staff (or if you are a real glutton for work, do it yourself) scan all of the NARM Guides and compile a list of all the additional documents you will need to perform the portion of the evaluation you selected to do in Step 3. As a hint, there are a maximum of eight additional documents needed. It would be easy enough to list these, but it is felt that there is a confidence-building factor in having you compile your own list. Once you have the list of documents you need, turn to page 0-5 of the Introductory NARM Guide for the addresses from which to order them. Then order them. (Ideally once you receive these documents, you, or a member of your staff, will scan them before they are placed in the bookcase.)

STEP 4a

Now comes the hard part. You are all full of new knowledge gained in Steps 1, 2, 3, and 4 and bursting with the self-confidence gained by completing Step 4, but no one calls upon you to exercise this newly acquired knowledge and confidence. You sit and wait and wait and wait. Step 4a may last for weeks, or months, or maybe even a year or two, but you can feel proud and smug because you can throw around au courant anacronyms like NARM, ANSI, and so forth, and furthermore, you will know what they mean. If you are lucky, Step 4a will not last too long, and you will get to proceed to Step 5.

STEP 5

You discover or are told about the existance or proposed existance of an unevaluated NARM product that is or will be manufactured, assembled, or distributed by a company located in your State. The NARM product may be brought to your attention by a product catalogue, one of your agency's covert agents, or even by the company that wants to manufacture, assemble, and/or distribute the NARM product. Now it is panic time! You have been busily going around impressing your fellow employees, friends, and neighbors, but now you have got to put out or shut up! Remain calm and proceed to Step 6.

STEP 6

After the NARM product is discovered, you must tell the company that its NARM product must be evaluated. Just remember, if this is the first NARM product you have been called upon to evaluate then the probability is extremely high that it is also the first time the company has been faced with the prospect of having a NARM product evaluated. (If you have already evaluated one or more NARM products, you will know exactly what to do and how to do it.)

STEP 7

When the company has been told it must have its NARM product evaluated, the first question that will normally be asked is, "What information do I need to submit?" In reply you rush to the NARM Guides and pull out the NARM Guide that is applicable to the product and hand it to the company's representative. (A State may wish to issue its own NARM Guides which directly reference that State's regulations.) Now the ball is in the company's court.

STEP 8

While the company is trying to recover the ball and frantically reviewing its product design to see if it was really financially necessary to eliminate all that shielding and other safety features, you have a slight respite. During this time, you should review the appropriate NARM Guide or Guides and alert the BRH if you want it to assist you in the evaluation.

STEP 9

Upon receipt of the company's package of information, documents, and drawings, you proceed step-by-step through the company's material to see that the information called for in the appropriate NARM Guide has been submitted and that the product meets or exceeds the design, construction, and operational criteria specified in the NARM Guide and the additional referenced documents. Do not forget that if you have solicited the BRH's help back in Step 8, you should send a copy of the company's package of material to the BRH so it can get going on its portion of the evaluation.

You may have to ask the company for additional information, for design changes, or for improvements in design, instruction or safety manuals, labeling, and so forth. This is normal; do not be hesitant about requiring the company to furnish additional data or information.

STEP 10

When you have satisfied yourself, or yourself and the BRH, as the case may be, you should prepare a Product Evaluation Sheet for the "Radioactive Materials Reference Manual" (RMRM) (2). The format and instructions for preparing the Product Evaluation Sheet are in the Introductory NARM Guide. (You should remember this from Step 2.)

STEP 11

Next you prepare a radioactive materials license or letter of authorization for dispatch to the company. NARM Guide 13: "Standard NARM Licensing Conditions" hopefully will be published in the near future to assist you in the preparation of these. Draft copies of NARM Guide 13 were mailed to each State some time ago, and are suitable for use until NARM Guide 13 is officially published.

STEP 12

As soon as the radioactive materials license or letter of authorization is mailed to the company, mail a copy of the Product Evaluation Sheet to the BRH (check the Introductory NARM Guide for the address) so that the BRH can send it to each State to put in their RMRM.

STEP 12a

Breathe a sigh of relief! You have done a NARM product evaluation! Now you can swagger out with enhanced confidence knowing that not only do you have the technical knowledge to perform a NARM product evaluation but that you have the practical, hands-on experience of having actually done an evaluation of a NARM product. You can walk with your head held high, secure in the knowledge that you have met the prerequisite for membership in that small, elite goup of State radiation control program personnel who have evaluated a NARM product and put your name on the line before the entire United States via the Product Evaluation Sheet that the product is acceptable for routine licensing and distribution.

REFERENCES

1. Conference of Radiation Control Program Directors, Inc. Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) (HEW Publication (FDA) 77-8025). Washington: U.S. Government Printing Office (1977).

2. Bureau of Radiological Health. Radioactive Materials Reference Manual. Rockville.

DISCUSSION

MR. SPELL: I would like to ask what suggestions you have for when you discover a product that needs an evaluation when a manufacturer is in another State and after making a request you get no results?

MR. BAILEY: In the past, we have performed our own evaluations on what were described as unique products, one of a kind installations. The Task Force's recommendation is that if it is not a unique product, that you go back to that company and tell them they have to get it evaluated by their State. There is a mechanism which is as simple as the State writing one or two letters. We had some licensees located in a Non-Agreement State that we had licensed to distribute generally licensed devices, and the problem is that we are saying that those products were essentially acceptable but we had never been to their facility. We had no way of checking their quality control; we had no way except our own inspection of their devices in Texas to know whether they were labeling them properly. So I think it is a bad deal to evaluate a product that is going to be routinely distributed if that distribution or manufacturing occurs in another State. One of the things we are considering is taking the list of products that have not been evaluated and after our second letter to the States trying to get them to evaluate their products is to send the States a third letter. Essentially that is what we are forced to do in Texas; to send our third letter to the State saying "look we have these companies that are distributing radioactive materials as far as we know and we propose to send that company the enclosed letter unless we get them evaluated." That enclosed letter essentially tells that company that their product is no longer welcome in one State because they are unevaluated.

LICENSING STATE CONCEPT - How it would be IMPLEMENTED

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Environmental Health Protection
Colorado Department of Health

(Presented by James L. Montgomery)

Recognized naturally occurring and accelerator-produced radioactive material (NARM) regulation is coming of age. The efforts of Task Force No. 1 of this Conference has provided guidelines for regulatory programs. Now, with the official recognition of Licensing States in the Suggested State Regulations for the Control of Radiation, 1978 edition, such programs can truly accomplish this important task with greater efficiency. This is particularly true in the reciprocal recognition of licenses, which heretofore was problematic.

While the NARM guidances and the Licensing State provisions are important, they are only the initial steps toward the goal of uniform regulation of radium and other such materials in this country. Implementation of the guidelines and a uniform compatible regulatory process, including enforcement, is essential if the overall effort is to be successful.

Following discussions of the Executive Board of the Conference, an ad hoc committee, and conversations between the chairperson and representatives of the sponsoring agencies with myself, an operational scheme has been devised that will allow for a voluntary regulatory program review process.

NARM has no legislated "home" in a Federal agency. However, the provisions of Federal law do allow for a State to request a program review. In the case of NARM regulating States (Licensing States), this request would be addressed to the Bureau of Radiological Health. Copies of this request from States that are also Agreement States with the Nuclear Regulatory Commission should be sent to the Commission. I would also recommend that copies of all requests be sent to the Conference.

In Agreement States, because of the annual program review requirement, the Nuclear Regulatory Commission has agreed (verbally) to conduct the NARM program review at the same time as their annual review effort. In the case of the Licensing State that is not an Agreement State, the Bureau of Radiological Health could honor the request and conduct a similar review of the regulatory process.

To facilitate setting up the review process it has been suggested that the reviewing agencies use the procedures developed over the years by the Nuclear Regulatory Commission staff. This would also allow consistency for those States who are both Agreement and Licensing States.

The results of these requested regulatory program reviews would be provided to the requesting States.

Positive findings of acceptability could be released by the respective State to the Conference and published in the FEDERAL REGISTER under the auspices of the Bureau of Radiological Health. In the event that there are programs that do not meet the criteria, the Conference's Executive Board may, at their discretion, act as an arbitrator in resolving the differences of opinion between the individual State and the reviewing agency.

The voluntary review process of the entire NARM regulatory program will resolve several items of concern to us all. It will provide a mutual review process whereby the individual NARM program will be scrutinized and judged against criteria already in existence. Secondly, the results of the finding of program acceptability will be public and therefore the reciprocal recognition of licenses from NARM regulating States would be on a better footing; that is, recognized by regulation and a program review process. Thirdly, the uniform regulation of NARM throughout this country should be greatly improved.

I would recommend that the Licensing States request an annual review of their NARM program and that the release of positive findings be coordinated for publication between the Nuclear Regulatory Commission and the Bureau of Radiological Health.

I strongly support and endorse the Licensing State concept and the program review process proposed because I see many side benefits for the participating States and the nation as a whole. It might also lead to the recognition of the Licensing State by the Occupational Safety and Health Adminstration and the Environmental Protection Agency in its Resource Conservation and Recovery Act of 1976 efforts on radioactive hazardous waste. I am extremely hopeful in this regard. However, should the review proces fail to achieve its goal of providing uniform regulatory practices and acknowledgment of acceptable programs, in all good conscience I would have to withdraw my support and recommend the deletion of the Licensing State concept from the Suggested State Regulations.

To finish my talk on a very positive note, attached to this speech is Colorado's request to Mr. John Vilforth, Director, Bureau of Radiological Health, requesting the NARM program review and the publishing of positive findings of program acceptibility under the Nuclear Regulatory Commission Agreement State program review criteria, with copies to the Nuclear Regulatory Commission and the Conference. I sincerely hope you will join me in this voluntary effort of extreme importance to us all.

DISCUSSION

MR. BAILEY: This has been a matter of controversy in that the Licensing States were not evaluated by anyone as the Agreement States are by NRC. I think Colorado is very lucky in being able within its department to have the stature to be able to invite an outside agency to criticize your organization and tell your bosses where you are deficient and the fact that you need more money. I wish all the States were and I am afraid all of them are not. I think that this voluntary requesting of a review might in fact be detrimental to some State programs and may be another way that one could go. BRH now is accepting State inspections for Federal compliance on the performance standard. If some of the things that we are trying to do with the Bureau of Medical Devices through BRH on medical devices containing NRAM go through then they will essentially be accepting State evaluation of devices. I feel that in essence then the Bureau would have very good justification for an annual review of the program and would not have to place the program director in what I consider a very unenviable position of having to ask outside people to come in and evaluate. I would like to know if you have any comments on that.

MR MONTGOMERY: Of course, this outside agency coming in is what the Agreement States have to live with whether we like it or not and I think your comment is well taken because it is a voluntary program. I supppose there would be some problems with certain States. I cannot really imagine all of the Licensing States accepting the voluntary program but I hope many of them do.

MR. TAPERT: The Bureau did receive the letter from Al Hazle and has responded. So if Jim wishes to say anything about the reply he may wish to do so.

MR. MONTGOMERY: Basically, Al Hazle was under the impression that the Bureau would agree or had agreed to form the review. Al Tapert informs me that this is not necessarily so, that they are still looking at some of the details of how this would be implemented and exactly who would do what, where, and when. So that is basically what the letter says and the Bureau did express their interest in working and cooperating towards this end.

The DISCOVERY and ASSESSMENT of FORMER RADIUM PROCESSING SITES

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Colorado Department of Health
(Presented by James L. Montgomery)

During the last week of January 1979, Al Hazle was contacted by Don Hendricks, ORP, EPA/LV. Dr. Hendricks informed Colorado of his reviewing of U.S. Bureau of Mines Bulletins 70, 103, and 104, which related to radium extraction from uranium ores and of a major facility operating in Denver 1914 to 1917. With the provision of the documents and with the assistance of Paul Smith of the EPA Region VIII Office, the location of the National Radium Institute was identified from the Denver Public Library's City Directories from that era.

A survey was performed on the site and Colorado Department of Health representatives assisted the Robinson Brick and Tile Company (present occupants of the site) in preparing and disseminating an appropriate news release. The news of such a find prompted further investigation by reporters resulting in the listing of at least 10 other sites in need of investigation. With the anticipation of still further sites and a wide spread investigation, Department mobilization was activated.

Further finds prompted the need for outside assistance. Federal, State, local agencies, and others joined in the effort. Specialized equipment was made available.

While I will shortly address the findings, my main emphasis in this paper will be on the cooperative efforts extended to the Colorado Department of Health, Radiation and Hazardous Wastes Control Division.

Staffs from the following organizations participated, provided information or provided equipment.

- Colorado Department of Health
    - Radiation and Hazardous Wastes Control Division
        - Radiation Control Section (Health Physicists and Technicians)
        - Solid Wastes Management Section (Engineers and a Geologist)
    - Water Quality Control Division (District Engineers)
    - Laboratory Division (Chemists and Technicians)
    - Consumer Protection Section (Sanitarians)
    - Epidemiology and Chronic Disease Control Division (Epidemiologists)
- Colorado Department of Natural Resources
        - Colorado Geological Survey
        - Division of Mines
    - Colorado Department of Highways (Drill Rigs)
    - Colorado Department of Labor and Employment
        - Oil Inspection (Drill Rigs)
- Colorado Department of Law
- U.S. Environmental Protection Agency
    - Office of Radiation Programs/Las Vegas
    - Region VIII
- U.S. Department of Energy
    - Division of Environmental Control Technology/HQ
    - Las Vegas Operations
    - Rocky Flats Area Operations

- Contractors (EG&G and Rockwell International)
- U.S. Federal Aviation Administration
- U.S. Geological Survey
- U.S. Nuclear Regulatory Commission
  - State Agreements Branch
- Region VIII Interagency Regulatory Liaison Group
  - Environmental Protection Agency
  - Consumer Product Safety Commission
  - Department of Agriculture
  - Department of Health, Education, and Welfare
  - The Occupational and Safety and Health Administration
  - The Mine Safety and Health Administration
- The City and County of Denver
  - Denver Health and Hospitals
  - Office of Civil Defense
  - Denver Water Department
- Jefferson County Health Department
- Boulder County Health Department
- El Paso County Health Department
- Local Network Radio and Television
- Local Press
- The Office of the Governor of Colorado
- The Colorado Congressional Delegation

The Radiation and Hazardous Wastes Control Division of the Colorado Department of Health was assigned the lead responsibility for organizing the investigation effort. All teams regardless of responsibility were assigned a health physicist from the division.

While most of the agencies involved provided personnel, it is noteworthy to mention the euqipment that was made available: scintillometers from the Grand Junction Remedial Action Program, which were specifically calibrated for radium deposit detection; G-M meters from the Denver offices of the Department; alpha survey meters and alpha wipe field analysis capability from the Rocky Flats Plant; scintillometers, pancake probes, and a gamma scanning van from EPA/Las Vegas; a gamma mapping helicopter and portable gamma spectrometers manned by EG&G personnel; manned down-hole dogging tools and spectrometer capabilities from USGS; and drill rigs with personnel from the Colorado Departments of Highways and Labor and Employment. It also is important to add that the efforts of the Office of the Governor and the Congressional Delegation assisted our Department in obtaining outside assistance previously unavailable.

The cooperation of the news media and the property owners greatly expedited the surveys and resulted in the gathering of some important bits of information in a relatively short period of time (2 months).

While part of the investigation is still continuing, some of the findings are of particular note. Thirty-seven locations have been identified as being contaminated because of radium extraction or processing. Of these 37, 1 is in Grand Junction, 3 are in Montrose, 2 are in Boulder, and 31 are in Denver. Of the 37 locations, 9 are alleys or streets, 10 are vacant lots or open areas, 2 are railroad right-of-ways, 6 are commercial structures, and 10 are combinations of structure and lot involvements.

Deposits are sometimes relatively small such as a shallow surface deposit or a spot of radium contamination on a window sill. Others involve high level radioactive sumps at depths of 18 feet, and multistoried buildings with contamination spread throughout and incorporated into the structure and waste plumbing.

There is no concern for an imminent health hazard situation. While exposure levels at discrete spots at contact with the contamination might be quite high, consideration of occupancy times and modes, averaging of reading, correction of readings for energy dependence of the instrument (over-response) indicates that the maximum additional exposures from both gamma and radon daughter results in a doubling the natural background level.

Using the criteria for the Grand Junction Remedial Action Program, Colorado Guidelines for Abandonment of facilities and equipment (similar to NRC guidelines for plutonium), and EPA proposed hazardous waste regulations, all sites with the exception of the streets and alleys would require remedial action. As the streets and alleys are a controlled situation, remedial action is not necessary unless the site is excavated. The city and the utility companies have been informed of the locations of these deposits. Owners of the locations having contamination have been informed of the situation.

The current estimates for removal of the contamination from the sites is $1 million. If the contamination is to be hauled in containers to Beatty, Nevada, for disposal, the cost of containers, transportation and disposal charges might approximate $3.5 million. Disposal at a Colorado uranium mill would involve transportation costs of about $150,000.

As to who would bear the cost of any remedial action, there currently exists no State or Federal legislation which directly addresses this situation. Certain Congressional committees are interested in reviewing the situation but the Three Mile Island incident has taken priority.

BIOLOGICAL INDICATORS as an AID in DOSE ESTIMATION

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INTRODUCTION

In the practical world of regulating, enforcing, and managing maximum permissible dose limits, incidents occur in which there are conflicting stories as to what exactly occurred, and whether in some cases an incident has occurred at all. This paper reviews two cases in which conflicting information regarding exactly what occurred during a reported incident were resolved, or an attempt at resolution was made by falling back on biological dose estimators--mainly chromosomal analysis and differential white cell analysis.

Today, most health physicists are not familiar with biological indicators because this is an area of health physics that is mainly the field of a physician, as it rightly should be, and also controls are such as to usually make biological indicators unmeaningful. On the other hand, as program directors, we should be aware of these indicators because we are in a position to recommend to management how far he should go in estimating dose where this information is unavailable or ambiguous. On a longer term basis, such information will be useful in deciding when an exposed individual can be returned to radiation work and also the future dose management of such an individual.

One of the older biological indicators is the differential white cell count. It was not uncommon in pre-1940 era to determine for hospital radium workers when they should have a vacation or at least be removed from radiation work based on the trend in the differential white cell count. Some facilities have continued even to the present time to have some type of blood cell count done on a periodic basis. I can state from personal experience that this has lent a note of assurance to persons working with radiation and when I recommended that the frequency of white cell counting be reduced, or eliminated there was such an objection that it had to be reinstituted on an annual basis. Therefore, even negative or normal biological results give reassurance to radiation workers.

A newer technique is cytogentic analysis. This technique involves the analysis of aberrations or abnormalities in nuclear chromosomes and, as such, it is assumed to indicate biological changes at a fundamental cellular level, namely damage to deoxyribonucleic acid (DNA). Such damage could obviously affect the proper functioning of the cell and also such damage is transmitted to future generations of such cells. Although it should be emphasized that how the abnormalities might affect the general health of an individual is uncertain at present.

Cytogentic Technique

Cytogenetic analysis is a fairly old technique and is continuing to evolve as more information becomes available on the chemical make-up of the cell nucleolus. It was used in the 1930's to observe damage resulting from ionizing radiation at the cellular level. One problem with the technique is that it is manpower intensive and probably this in itself is the main reason why it has not found wider application. The time needed to score 150 cells--about the minimum number necessary to obtain a dose estimate--takes 1 man-day effort.

Attempts to automate, by using a computer to score cells, has not drastically reduced the time required. Therefore, one must realize that this analysis is an expensive one to perform and will probably not become in the foreseeable future as routine as a complete white cell count.

Case History No. 1

With that general introduction, the first case history will be described. This case involved a reported industrial radiography incident based on a high film badge reading of 54.5 rem. The badge belonged to D.M., a radiographer, but he could remember no occasion or incident during the month of May when the badge was worn that might have caused such a high reading. I might add an additional twist to this case. The first telegram to the radiography firm from the Film Badge Company indicated an exposure of 6.5 rem. A later telegram report on same day gave the exposure as 54.5 rem. Upon receipt of this report, we requested a complete medical exam including CBC, a check by a physician of the hands and body of the radiographer for any skin erythema, and an estimate of the photon energy based on film badge results.

The radiographer was obviously very much concerned because, as he claimed, he had no recollection for the month of May of any unusual situation where such an exposure might have occurred.

In fact, he went immediately to the emergency room of the local community hospital upon receipt of the report and had a blood count taken, which turned out to be normal. We received a report of this incident through the State Health Department and only about a day later received the incident report from the firm.

An investigation on our part indicated that at no time during the month of May was D.M.'s pocket dosimeter off-scale, and his total exposure was 150 mR as estimated from pocket dosimeter reading. On all 16 days that he performed radiography there was a record of surveys for the day's radiography job.

He claimed that he had no diagnostic x rays during the month. The report we requested from the Film Badge Company stated that there were no shadows on D.M.'s film and that the photon energy was high. The Film Badge Company states firmly that the 54.5 rem was correct. At this point, we did not know who to believe. Therefore, we requested additional biological tests, such as chromosomal analysis to be conducted.

On July 10, about a week and a half following the high film badge report, venous blood samples were collected from D.M., a fellow radiographer, R.D., and a control blood sample. The blood samples were packed in ice and air shipped to Pittsburgh for analysis by Dr. Neil Wald at his Cytogentics Laboratory. Dr. Wald exposed, in vitro, a fraction of the blood collected to Ir-192 to obtain information on the type of aberrations to be expected and to get an idea of the calibration factor for Ir-192 photons. D.M. had the following results based on an analysis of 200 lymphocyte cells: 1 isochromatid break, 1 ring chromosome, and 6 chromosome fragments.

The results indicated a very low level of exposure over a long period of time and if abnormalities were assigned to a single exposure it would be in the range of 15-25 rads. The one ring chromosome was found in a cell with no accompanying fragments. Therefore, it was assumed to arise from past exposures rather than any recent exposures. D.M. stated that his chemical exposure was limited to developing and fixing solutions.

R.D. had an estimated exposure of 230 mR, film badge, and 168 mR, pocket dosimeter readings during May and he had the following results based on analysis of 200 lymphocytes cells: 3 isochromatid breaks, 3 dicentrics, 4 chromosomal fragments .

R.D. had more abnormalities than D.M. and his exposure would be 25-45 rads if all abnormalities were ascribed to a single incident. Figures 1 and 2 depict cell chromosomes with rings and dicentrics present. Two cells with dicentrics had fresh chromosome fragments, which is indicative of fresh damage. On further inquiry, it was found that R.D. had recently received dental and back x rays. In addition, he had exposure to gasoline, trichlorethylene, and phenylbutazone and, in his radiography job developing and fixing solutions.

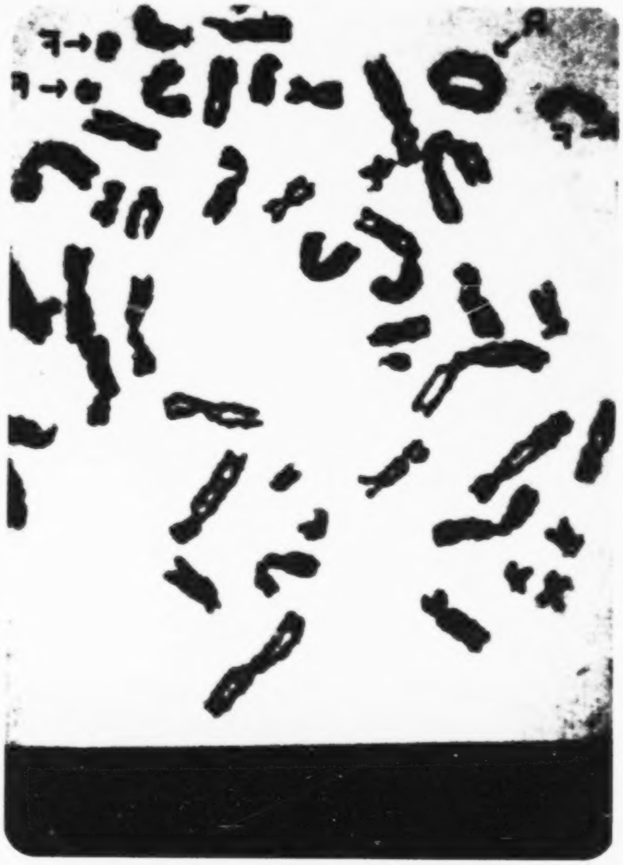

Figure 1. Cell chromosomes with ring chromosome and two chromosomal fragments present.

The medical x rays and chemical exposures probably contributed to R.D.'s high number of chromosomal abnormalities in the 200 cells scored. The control had no chromosomal abnormalities in the 200 cells scored.

In October we received a letter from Radiography Firm requesting that the 54.5 rem exposure not be added to D.M.'s lifetime exposure record and that he be permitted to return to radiation work. Both requests were granted. Unfortunately, unresolved was how and where D.M.'s badge received the film darkening, but we felt relatively confident based on the cytogenetic results that D.M. had not received such a whole body exposure recently.

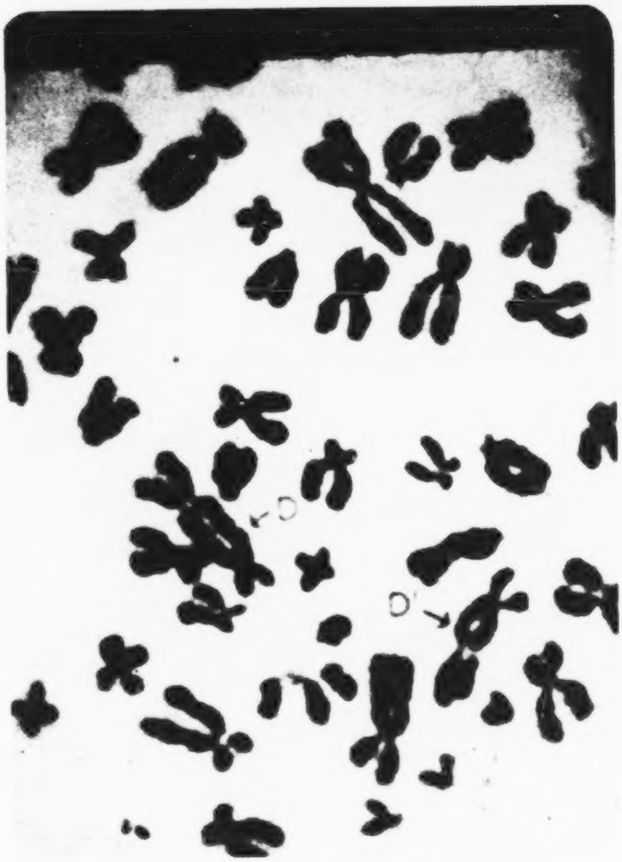

Figure 2. Cell chromosomes with two dicentric chromosomes present.

Case History No. 2

In a way the case No. 2 is the opposite to case No. 1. The film badge exposure recorded a value of only 0.43 rem but it was suspected that an incident occurred with an estimated partial body exposure of 16.7 rem.

In this case an industrial radiographer, D.K., was taking radiographs of a plane with a Picker x-ray unit operating at 95 kVp and 7 mA. The x-ray unit was mounted on a cart. D.K. thought he saw the x-ray indicator light go off and he stepped up to the cart and was proceeding to move the x-ray head to another locaion when his assistant, originally stationed on the other side of the aircraft, shouted to him that the x-ray machine was still on. At this point, D.K. immediately left the area and his exposure time was estimated at between 30-60 seconds.

Because the film badge was located on the radiographer's waist the scattered x rays were partially shielded from the badge by the x-ray head. A reenactment of the incident indicated that D.K.'s upper torso received a dose estimated at 16.7 rem. In this case the D.K.'s total white cell count was as follows: 4 days post exposure, 6000 cells; 6 days post exposure, 8800 cells; and 10 days post exposure, 8800 cells.

A pre-employment white cell count was 10,400 cells.

One might attribute on somewhat tenuous grounds the white cell count dip on 4 days post exposure to physical stress of the exposure; certain differential white cell lines showed a dip on day 4 post exposure as well. But as there is normally a wide fluctuation in the WBC count one can only state with certainty that D.K.'s WBC count was in normal range and that his exposure was certainly less than 25 rem.

D.K.'s chromosomal analysis indicated no chromosomal abnormalities in scoring 125 cells and this result also indicates an exposure of less than 25 rem. The partial body exposure makes this method less sensitive than in the case of whole body exposure.

D.K. was removed from radiation work for a period of 1 year by his employer and in addition the firm strengthened its x-ray radiography procedures by requiring the radiographer to confirm that x-ray beam is off by a survey meter check before reentering radiation area.

Discussion

Case History No. 1 is an excellent example of what can be accomplished by cytogenetic analysis as well as its pitfalls. Since the technique is relatively uncommon in this worker population, we did not expect that D.M.'s fellow radiographer might have a comparable number of unstable aberrations in his lymphocytes. But, his non-occupation chemical and x-ray exposures would explain his higher than expected result. Most of the unstable aberrations are gradually eliminated from the lymphocyte cell population with half lives estimated at between 2-3 years in the absence of additional exposures (1).

Two recent articles have underscored the potential value and importance of chromosomal analysis and its use should expand in the radiation worker population (2,3). In Evans (2), a linear relationship was obtained between the number of cells with the unstable abnormalities (dicentrics, rings, and fragments) and dose with all exposures within the recommended maximum permissible dose of 5 rem per year. It was only possible to obtain this relationship by lumping all of the results obtained over a 10-year period and involved an analysis of 43,715 cells. Historically when this was done with differential white cell counts and bilobed nuclei a similar dose dependent relationship was also noted (4). Consequently, the continued importance of the differential white cell count should also be stressed. In the case history No. 2, the flat trend of the differential white cell count result (except for the one immediate post-exposure) and the negative cytogentic result indicated with confidence the low dose that was received.

While in only rare instances can one relate a chromosomal abnormality to a specific disease, evidence is mounting that the DNA damage as represented by the abnormality is a precurser to serious diseases, such as cancer (3). Consequently, such analysis may assume additional importance in the future.

Conclusion

Biological indicators such as differential white cell count and chromosomal analysis can be used in a State's radiolgocial control program as excellent indicators of the overall health status of radiation workers. They can be used to make recommendations to management on when an exposed individual can be safely returned to radiation work. Finally, these tests are a useful tool in substantiating physical dosimetric measurements. They are not a panacea and will not precisely indicate an individual's exposure below 50 rem. Biological indicators also give positive readings for many causes, and exposures of workers to chemical and physical stresses besides ionizing radiation should also be documented where possible.

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REPORTING of ENVIRONMENTAL RADIATION MEASUREMENT DATA

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The Task Force on Radiation Measurements of the Conference of Radiation Control Program Directors in its first report to the National Bureau of Standards (NBS) in February 1977 recommended that:

> "NBS in cooperation with EPA should be designated as the Federal agency responsible for coordinating efforts among the Federal and State agencies to immediately develop a uniform data reporting system so that present environmental data which are being generated throughout the country can be utilized and evaluated in terms of possible population exposure."

At approximately the same time, a Health Physics Society ad hoc committee was organized for the purpose of upgrading environmental radiation data. One of the 9 project objectives identified by that committee had a scope nearly equivalent to the Task Force recommendation. Specifically, the HPS committee identified the need to "establish more standardization in data reporting conventions including the definitions of detection limits and the treatment of results at or below these limits." As a result, NBS agreed to coordinate and implement the project under the auspices of the HPS committee and an appropriate subcommittee was formed to serve as a working group (1). This subcommittee received very broad national participation by representatives of private industries, government contract laboratories, State governments and Federal agencies including DOE, EPA, NBS, and NRC.

A draft of a document, A Guide and Recommendations for Reporting of Environmental Radiation Measurements Data (2), prepared by the subcommittee has been completed and distributed to a wider audience for review and comment. This guide and its detailed recommendations are intended to be useful and specific. It is not intended to be a general or exhaustive theoretical treatment of measurement results, but rather to serve as a practical guide to treating and reporting environmental radiation measurements data. A tutorial philosophy and approach was adopted because it was envisaged that many of the intended users would be unfamiliar with some of the relatively complex concepts and subjects covered in the Guide. Emphasis throughout has been placed upon obtaining solutions and not just reidentifying the problems associated with reporting data. Present data reporting practices are summarized and evaluated, and their deficiencies are examined. In those cases where current practices are unjustified, the reason for alternative approaches are carefully explained. Nearly 30 specific recommendations for a uniform method of data reporting are presented and justified. From the onset, the subcommittee recognized that its recommendations will not be adopted unless they are strongly justified. Additionally, the Guide contains considerable supporting materials so that it may be used without recourse to other reference sources and extensive examples to demonstrate the practical use of the recommended methods.

The complete Guide will be published as an NBS Special Publication (2) and will be available in the Fall of 1980. A condensed version will be included, along with eight other reports, in a publication of the Health Physics Society that will present the combined output of the committee on upgrading environmental radiation data (3). Highlights from the Guide which are still provisional follow.

OVERVIEW

There are three primal requisites to reporting measurement data. The reported value of a measurement result must always:

1. be unequivocal and properly dimensioned (i.e., the units must be clearly understood and suitable for the value);
2. be expressed in an appropriate number of significant figures; and
3. include an uncertainty statement (whose meaning is also unambiguous).

Mistreatments of conditions (1) and (2) are usually not the most serious failings in data reporting. There is, however, considerable variation in the practices recommended and required by the various Federal agencies concerned with environmental radiation data reporting. Recommended conventions to satisfy these conditions are covered in Parts I and II of the Guide, respectively.

Failure to satisfy condition (3) is probably the most frequent abuse and of greater concern. Unfortunately, almost all environmental radiation data presently being reported fall into one of three categories:

i. the value is reported without stating the uncertainty;

ii. the uncertainty is reported, but it is not specified;

iii. the reported uncertainty is specified, but is based on an incomplete assessment.

Further, Federal practices pertaining to the reporting of uncertainties not only contribute to these abuses, but are also as diverse as the number of agencies and requirements specified within an agency's regulations. Recommendations for assessing, propagating, and reporting uncertainties are given in Part III of the Guide.

Perhaps the most nonuniform practices in environmental radiation data reporting are those involving detection limits. This and the treatment of results at or below these levels are covered in Part IV.

I. DIMENSIONING (UNITS)

As outlined in the Overview, the first requirement for the reporting of environmental radiation measurements data was that reported values must "be unequivocal and properly dimensioned." That is, the units for the values must be clearly understood and must be suitable for the value.

A survey and evaluation of typical units currently in use indicates that there are considerable variations in practices. This existing multiplicity is both needless and confusing. It would be beneficial and helpful (to both laboratories and data users) if the number of units in use were reduced to a smaller consistent set. This goal of greater uniformity could be accelerated by the encouragement of the national use of the metric system, formally called the International System of Units (SI), and by the use of standard metric practices and conventions. A recommendation to expedite the transition to SI units may be a bitter pill for many people to swallow. The familiar "curie," "roentgen," and "rem" are deeply entrenched within the radiological sciences and radiation fields, and will not be easy to forsake. This natural reluctance to change can be appreciated, but the eventual conversion to SI is inevitable and must be recognized. In addition to our national commitment to the SI, there are many advantages to its use. These advantages are discussed and summarized in the Guide and will not be detailed here. For environmental radiation measurements data, we are primarily concerned with the units for radioactivity, exposure, absorbed dose, and dose equivalent. The status of each of these, in terms of both the old units and new SI units, is considered with the Guide.

The Guide recommends that data reports should convert to the SI base and derived units for radiation quantities as soon as it is technically and economically feasible. In view of existing governmental regulations and data-reporting requirements, it is, at present, neither feasible nor economically justifiable to completely and immediately change over from old to new units. This change will require familiarization and a transition period. Efforts to plan and implement a safe and orderly transition to SI units should be initiated by concerned laboratories, independent organizations and governmental agencies to aid and expedite the transition.

A consistent set of units for various environmental radiation quantities (for both the old and new SI units) is contained with the Guide and should be employed for data reporting. In addition to presenting these recommended units, the Guide also contains (1) a summary of dimensioning conventions including the treatment of compound units, multiples and submultiples of units, and special units, (2) guidelines for expressing results in exponential notation, (3) some considerations for the transition to the use of SI units, and (4) a discussion of some unsatisfactory current practices such as the extensive reporting of "gross activity" measurement results in units of activity.

II. SIGNIFICANT FIGURES

The second requirement (outlined in the Overview) for reporting measurement data was that the reported value must be "expressed in an appropriate number of significant figures." Fortunately, this is nearly universally recognized, and is seldom a problem.

The "number of significant figures" refers to the number of numerical digits that is used to express the value. It is obvious that this number must be reasonable, and must not mislead or imply fictitious accuracy in the reported value. An "appropriate" number of digits (or significant figures) is that which is warranted by the accuracy of the reported value. That is, the appropriate number of digits to be retained in the reported value depends on the magnitude of the total uncertainty (see Part III) attached to this value.

In general, environmental radiation measurements data seldom justify more than two or three significant figures for the value and one or two significant figures for the uncertainty. More significant figures should only be reported after careful consideration and a decision that the extra figures are indeed reportable. It is recommended that the uncertainty should be reported to no more than two significant figures, and the value itself should be stated to the last place affected by the qualification given by the uncertainty term. The value and its uncertainty must be in decimal agreement. Some consistent, well-developed rules for rounding reported values and their uncertainties to an appropriate number of significant figures are provided in the Guide.

These views are currently incorporated into most data reporting practices and regulatory requirements.

III. TREATMENT OF UNCERTAINTY STATEMENTS

Three of the more common abuses concerning the reporting of uncertainties for environmental radiation measurements data were summarized in the Overview. These abuses are addressed in detail within the Guide, and will not be considered here. It may be useful to state, however, the necessary conditions for avoiding their failings:

A REPORTED VALUE MUST INCLUDE AN ASSESSMENT OF ITS UNCERTAINTY.

THE REPORTED UNCERTAINTY MUST BE CLEARLY UNDERSTOOD AND MUST CONVEY SUFFICIENT INFORMATION SO THAT ITS MEANING, USING CORRECT TERMINOLOGY, IS UNAMBIGUOUS.

THE REPORTED UNCERTAINTY MUST BE BASED ON AS NEARLY COMPLETE AN ASSESSMENT AS POSSIBLE.

The first condition should be self-evident. A reported value without an accompanying uncertainty statement is for nearly all purposes worthless. The value is rendered useless because it cannot be put to use with any confidence. Although the particular form of the uncertainty statement may be dependent on the intended or ultimate use of the result, it is without debate that the value must include one.

The second condition is equally important. An unspecified uncertainty statement forces the user to speculate whether the quoted uncertainty is just the random uncertainty, whether it includes possible systematic uncertainties, and to what level of confidence the value can be ascribed. The possibilities are innumerable.

The third condition derives directly from the underlying philosophy of the Guide's approach to uncertainty statements. If the uncertainty is meant to be an estimate of the likely accuracy or the likely limits to the absolute error in the measurement result, then the uncertainty must be based on as nearly complete an assessment as possible. The uncertainty assessment must consider every conceivable or likely source of inaccuracy in the result.

The philosophical basis for this approach is contained within the following logical devolution.

1. A reported measurement result (x) of a quantity which is obtained by a given measurement process is used to estimate the true value (τ) of the quantity. This may be represented by

   $$x \rightarrow \tau$$

   where the arrow is read as "used to estimate." The true value is, of course, unknowable.

2. The accuracy of the measurement process is a measure of the ability of the measurement process to obtain closeness to the true value.

3. The absolute error of a particular result is just the difference between the measured or reported result x and the true value τ,

   $$\text{ABSOLUTE ERROR} = x - \tau.$$

   Obviously, the absolute error is also unknowable.

4. Limits to the absolute error may be estimated and inferred from the measurement process itself. The estimate of these limits is called the total uncertainty. The total uncertainty in the result (u_x) is used to estimate the inaccuracy of the measurement process; i.e.,

   $$u_x \rightarrow \text{INACCURACY}.$$

5. The total uncertainty can be thought to be comprised of two types, viz., random variability and systematic biases.

6. The random uncertainty is a statement of precision (or more correctly, of imprecision) and is a measure of the reproducibility or scatter in a set of succes-

sive independent measurements. Precision then is a measure of the closeness together. Random uncertainty components can be considered to be those sources of inaccuracy which can be and are assessed and propagated by statistical methods. Sample statistics, such as the standard deviation s_x, which are computed entirely from the measurement data, are used to estimate the population parameters such as σ_x. That is,

$$\underset{(\text{e.g., } s_x)}{\text{SAMPLE STATISTIC}} \rightarrow \underset{(\sigma_x)}{\text{POPULATION PARAMETER}}$$

7. A bias is a deviation from τ, which is always of the same magnitude and direction. It cannot be estimated or calculated solely from a given set of replicate measurements since each and every measurement is affected by the systematic bias in the same way. For a set of replicate measurements with a limiting mean of μ_x associated with the measurement of the particular quantity by the given measurement process, a bias is the difference between the limiting mean (μ_x) and the true value of the quantity,

$$\text{BIAS} = \mu_x - \tau.$$

8. For completeness, the systematic uncertainty components (δ) can be considered to be the residual set of the conceivable sources of inaccuracy which are biased and those which may be due to random causes or stochastic processes but cannot or are not assessed by statistical methods. Therefore,

$$\text{SYSTEMATIC UNCERTAINTY} \rightarrow \text{BIAS} + \text{UNEVALUATED RANDOM COMPONENTS}$$

9. The total uncertainty used as an estimate of the inaccuracy is then just some combination of the random and systematic uncertainties, i.e.,

$$\underset{(\mu_x)}{\text{TOTAL UNCERTAINTY}}\, f \;\; \underset{(s_x)}{\text{RANDOM UNCERTAINTIES}}\, , \;\; \underset{(\delta)}{\text{SYSTEMATIC UNCERTAINTIES}}$$

These concepts are summaried in Figure 1. The total uncertainty for a measurement result is ultimately used to estimate the accuracy of the result. It is obtained by combining the random and systematic components. The random uncertainty is a measure of precision in which calculated sample statistics are used to estimate population parameters. The systematic uncertainty includes sources of inaccuracy in addition to biases in order to obtain a complete accounting of all sources of inaccuracy in the total uncertainty. The very familiar "bull's-eye" example shown in Figure 2 should help illustrate the distinction between precision and systematic biases, and their relation to accuracy. The bull's eye of the target corresponds to the true value, and the six shots represent individual measurement results. The figure illustrates the concept of an inaccurate measurement due to imprecision, a precise but inaccurate measurement, and an accurate measurement. Inasmuch as accuracy requires precision, there is no such case as an accurate but imprecise measurement. It should be mentioned that a third category of conceivable sources of inaccuracy which has not been mentioned previously is that termed "blunders." These are the outright mistakes in the measurement process. If one or more blunders are known to exist, then the value should be discarded, or a correction should be applied to the measurement. One must recognize that blunders do and will occur. The Guide recommends establishing an internal system of independent checks on each stage of the measurement and data reduction system to detect and avoid blunders.

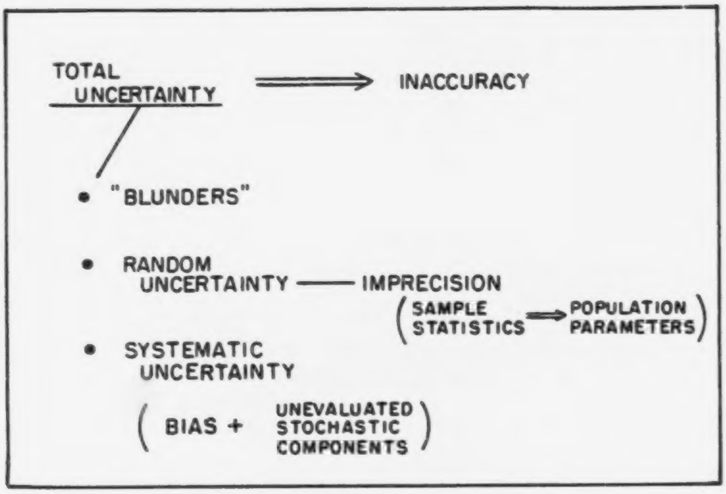
TOTAL UNCERTAINTY
INACCURACY
• "BLUNDERS"
• RANDOM UNCERTAINTY
IMPRECISION
(SAMPLE STATISTICS
POPULATION PARAMETERS)
• SYSTEMATIC UNCERTAINTY
(BIAS +
UNEVALUATED STOCHASTIC COMPONENTS)

Figure 1

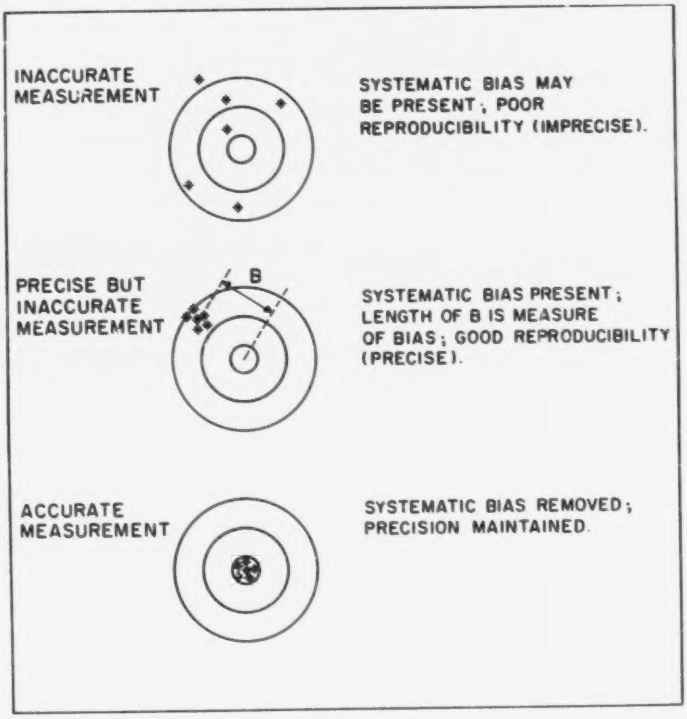
INACCURATE MEASUREMENT
SYSTEMATIC BIAS MAY BE PRESENT; POOR REPRODUCIBILITY (IMPRECISE).
PRECISE BUT INACCURATE MEASUREMENT
B
SYSTEMATIC BIAS PRESENT; LENGTH OF B IS MEASURE OF BIAS; GOOD REPRODUCIBILITY (PRECISE).
ACCURATE MEASUREMENT
SYSTEMATIC BIAS REMOVED; PRECISION MAINTAINED.

Figure 2

A large part of the Guide is devoted to the process of making a complete uncertainty assessment of all of the conceivable sources of inaccuracy, and the mechanics of treating the individual components from their initial assessment through their propagation. Figure 3 attempts to illustrate the concept of making this complete assessment, and the division of the sources of inaccuracy between the random and systematic components. Every conceivable source of inaccuracy should be classified into one of the two categories depending on how the uncertainty is estimated. Until combined for the measurement result, the individual uncertainty components in both categories should be retained separately.

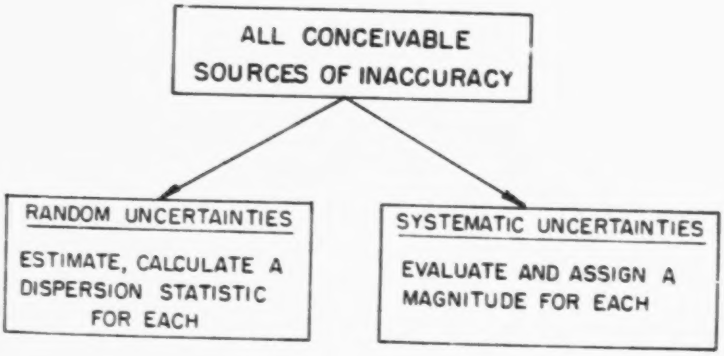
ALL CONCEIVABLE
SOURCES OF INACCURACY
RANDOM UNCERTAINTIES
ESTIMATE, CALCULATE A DISPERSION STATISTIC FOR EACH
SYSTEMATIC UNCERTAINTIES
EVALUATE AND ASSIGN A MAGNITUDE FOR EACH

Figure 3

Each random uncertainty component should be estimated in terms of its standard deviation, or the standard error of the mean for independent multiple measurements. These components are estimated by a statistical analysis of replicate measurements. The random "counting error" contribution may be estimated from single measurements by making the familiar Poisson assumption. Although the use of the term "counting error" will probably continue to prevail, the term is a gross misnomer. It takes into consideration only the random scatter about the mean from the radioactive decay process itself. To presume that this is the only source of random fluctuation in the overall measurement process is fatuous. Unfortunately, Federal guidance, as it pertains to reporting environmental radiation data, does not suggest otherwise. Other sources may be random timing uncertainties, random variations in the sample preparation, positioning of the sample at the detector, and so forth. The list is nearly endless. Many of these are addressed in a detailed appendix to the Guide.

The only way to realistically assess the overall random uncertainty is to make replicate determinations and calculate the standard deviation of the mean by the usual statistical methods. For reported values derived from several component quantities, the individual uncertainty estimates (obtained from replicate measurements for each independent variable) must be propagated to obtain the overall standard deviation of the final value. It is recognized that replicate measurements of environmental samples are uncommon and may not be feasible because of time and cost constraints. Yet an uncertainty assessment based on some procedure beyond calculating the square root of the total number of counts is clearly needed. The Guide recommends that the total random uncertainty be obtained by propagating the individual variances for each random uncertainty component. This would include not only the Poisson counting error and random uncertainty derived from the particular measurement under concern, but also the random components from corrections, constants, calibration factors, and any other measurements that make up the final result. These contributions may be combined by summing in quadrature or by the use of other propagation of error formulae given in the Guide. It should be emphasized that one benefit of making a complete assessment is that the process will require the evaluation and statistical control of many previously unevaluated measurement parameters. This will ultimately improve the quality of measurements and aid quality control within laboratories.

A clear distinction between random and systematic uncertainties is often difficult and troublesome. In part, this is because many experimental processes embody both systematic and stochastic (random) elements. The Guide contains a number of examples which attempt to clarify the distinction. In practice, the systematic uncertainties can be considered to be the residual set of conceivable sources of inaccuracy which are biased and not subject to random fluctuations, and those which may be due to random causes but cannot be or are not assessed by statistical methods. Although a general guideline for the approach to the assessment can be formulated, there are, unfortunately, no rules to objectively assign a magnitude to the systematic uncertainties. This is a subjective process based on the judgment and experience of the person making the measurement. The general approach is:

> Step 1 - Consider and identify all of the conceivable sources of inaccuracy. This requires a careful scrutiny of every detail and aspect of the measurement that can affect the reported value.
>
> Step 2 - From the above set, extract the blunders and those sources which can and have been (or will be) assessed by statistical methods (i.e., the random uncertainty contributions).
>
> Step 3 - Assign a magnitude to the conceivable limit of uncertainty for each of the remaining sources.

In estimating the magnitude of the systematic uncertainties, the Guide recommends that they be considered as upper bounds, overall, or maximum limits. By what method then should the magnitude of these maximum limits to the systematic uncertainties be assigned? It may be based on a comparison to a standard or verification with two or more independent and reliable measurement methods. Additionally, it may be based on judgment; based on experience; based on intuition; based on other measurements and data; or just a pure guess (which is not recommended, but may be better than nothing). Or it may include combinations of, or all of the above factors. The Guide also attempts to make this subjective process clearer through the use of examples of typical measurement situations. The fact that a conceivable source of inaccuracy is ascribable to random causes is not a sufficient condition for treating it as a random uncertainty in error reporting. It must be assessable by statistical methods derived from an analysis of repeated measurements. In the absence of this data, the effect of this random cause must be treated as a systematic uncertainty.

As described earlier, one can obtain a combined total random uncertainty contribution, stated in terms of some dispersion statistic such as the standard deviation (s_x). Conceptually, one can propagate and express the total random uncertainty in terms of some confidence limits at any chosen confidence level. This requires a number of assumptions, such as to the underlying population distributions, and can very rapidly become exceedingly complicated requiring computations based on the number of measurements involved in each random uncertainty component, the number of degrees of freedom, the magnitude of the counts in the Poisson counting error contribution, and so forth. One is therefore confronted with the choice between making simplifying assumptions (which ultimately may provide results that are misleading), or performing complex calculations (whose efficacy, in terms of the time and cost required, can be seriously questioned).

Additionally, one can obtain a list of each conceivable source of systematic uncertainty expressed as a confidence limit ($\pm \delta_j$), which can be at some high (say 99 percent or greater) confidence level.

Any approach to an overall uncertainty statement must consider (1) to what confidence level should the total random uncertainty s_x be reported; (2) how should the individual systematic uncertainty components (δ_j) be combined; and (3) how should the random and systematic uncertainties be combined to form an overall uncertainty. All three questions are interrelated. Underlying this entire discussion is the fundamental consideration that the way uncertainties are reported is dependent on their intended or ultimate use. A number of common practices and methods of combining the random and systematic uncertainty components were considered and reviewed in the *Guide*. It became apparent that there is no one clearly superior method out of the range of approaches to reporting an overall uncertainty. Yet, the diversity of current practices and methods either recommended or required by governmental bodies, or used by those who report data make it difficult if not impossible to combine or compare these data in a manner which would be useful for determining trends or possible necessary actions. There is, therefore, a great need for uniformity in the method used to report the uncertainties of environmental radiation data. In hope of achieving greater uniformity, a method, often termed the PTB approach (4), is recommended. In its simplest form, the random and systematic uncertainties should be combined to form an overall uncertainty in the result x by

$$u_x = \sqrt{s_x^2 + 1/3 \sum_{j=1}^{q} \delta_j^2}$$

where s_x is the standard deviation corresponding to the overall random uncertainty and δ_j is the magnitude of the estimated systematic uncertainty for each of the q systematic uncertainty components. Additional details and other special cases are given in the *Guide*. The recommended method requires that each reported measurement result include the value, the total random uncertainty expressed as the standard deviation, and a combined overall uncertainty. Examples illustrating the method are given in an appendix to the *Guide*. This recommended approach may not be the best for all purposes. It is intended to be useful and practical without imposing unnecessary burdens on the time, money, and personnel resources of laboratories. Adoption of this method may eventually demonstrate its most serious shortcomings and ultimately lead to better methods.

IV. DETECTION LIMITS

A myriad of vastly different expressions and definitions of "detection limits" are frequently encountered. Their meanings are often ambiguous, inconsistent, and incorrectly interpreted. Some of these include "detection sensitivity," "minimum detectable activity (or level)," "lower limit of detection," and "background equivalent activity." Some of the problems and inconsistencies in their use are addressed in the *Guide*.

Pragmatically, a detection limit is useful as a criterion for experiment design, comparison, and optimization purposes, such as in selecting among alternative measurement procedures. Additionally, detection limits may serve as guides which are set by regulatory bodies for establishing minimum acceptable detection capabilities for a given type of analysis. For the purposes of the *Guide*, the intent of detection limit calculations is to satisfy both of these uses. It must be emphasized that any calculation of a detection limit is at best only an estimate. Their use is limited to that of serving as guideposts only, and not as absolute levels of activity that can or cannot be detected by a counting system.

Much of the existing confusion with detection limits for environmental ionizing radiation measurements arises from not only the large number of different expressions that are in use, but also from incorrect interpretations and misapplications of some of the original definitions. In order to satisfy both of the above mentioned purposes, two distinctly different concepts are required.

The first is an estimated detection limit that is related to the characteristics of the counting instrument. It is not dependent on other factors involved in the measurement method or on the sample characteristics. It is a lower limit in the true sense of the word. Because of its current wide usage, the recommended term is the ESTIMATED LOWER LIMIT OF DETECTION (LLD).

BEST DOCUMENT AVAILABLE

The second concept is that most useful for regulatory purposes. It corresponds to a level of activity concentration that is practically achievable with a given instrument, method, and type of sample. It depends not only on the instrument characteristics, but also on many other specific factors involved in the measurement process, as well as the characteristics of the sample being measured. As such, it is not a limit at all, but only an estimated level achievable under a given set of practical conditions. The recommended expression for this concept is the ESTIMATED MINIMUM DETECTABLE CONCENTRATION (MDC).

The Guide recommends that only these two expressions be employed for all environmental radiation measurement detection limits. Both the LLD and MDC concepts can be based on a uniform consistent methodology. The use of this methodology with only these two expressions should help alleviate and avoid much of the existing ambiguity and misapplication. If the word "estimated" is emphasized and continually used in reporting a LLD and MDC, then their limited nature should be more apparent, and hopefully avoid the implication of an absolute significance in their numerical values.

Both the LLD and MDC may be defined a priori on the basis of statistical hypothesis testing for the presence of activity. This approach is common to both that of Currie (5), and Pasternack and coauthors (6). In this approach, the LLD should be viewed as an a priori estimate or guidepost of detection capability, and not as absolute levels of activity that can or cannot be detected. It is not intended to be an a posteriori criterion for the presence of activity. Similarly, the MDC should be viewed as an a priori estimate or guidepost of the capability for detecting an activity concentration by a given measurement system, procedure, and type of sample, and not as absolute activity concentrations that can or cannot be detected. The bases for the methods of calculation and derivations may be found in the Guide. With this approach and using the convention of accepting 5 percent risks of false detection (incorrectly detecting activity when it is absent) and 5 percent risks of false nondetection (a 95 percent confidence that activity will be detected when it is present), the expressions for the LLD and MDC, in the simplest cases, are:

$$\mathrm{LLD} = 4.65\,K\,s_b$$

and

$$\mathrm{MDC} = 4.65\,K^*\,s_s$$

where K is the proportionality constant relating the detector response (counts) to the activity (this normally would be only the detection efficiency or calibration factor for the instrument, and would not include other parameters such as the sample size, chemical yield, decay factors, and so forth);

s_b is the estimated standard deviation of the average blank background for the instrument;

K^* is the proportionality constant relating the detector response (counts) to the activity concentration in a given type of sample (this would include all of the necessary measurement parameters such as detection efficiency, chemical yield, absorption corrections, decay factors, and so forth); and

s_s is the estimated standard deviation of the average sample background for typical samples.

The estimated LLD for a given instrument, expressed in units of activity, should be calculated for each radionuclide, but is independent of the sample characteristics. In contradistinction, the estimated MDC for a given measurement procedure, expressed as activity per unit mass or activity per unit volume, should be calculated for each radionuclide for each type of sample. Calculation details for more complex cases are given in the Guide.

As stated earlier, the LLD is an a priori estimate dependent on only the instrument background and detection efficiency, and the MDC is an a priori estimate for a given type of analysis or measurement process under specified typical conditions. They are not a posteriori decision limits for every measurement. Therefore, they need not, and should not be calculated for each individual measurement. The practice of comparing a computed LLD or MDC for each measurement against the measurement result should be avoided. This has sometimes been employed to determine the "significance" of the result for reporting purposes.

If results below a particular computed LLD or MDC are rejected or excluded from data reports, serious errors and distortion in long-term trends could result. Consider the hypothetical situation illustrated in Figure 4. The background is represented by the probability distribution with mean μ_b and standard deviation σ_b. Similarly, a gross count is given by the distribution with μ_g and standard deviation σ_g. Thus, the net count, obtained by subtracting the background from the gross count, is the probability distribution with mean $\mu_n = (\mu_g - \mu_b)$ and variance $\sigma_n^2 = (\sigma_b^2 + \sigma_b^2)$. This net count distribution can be compared, as shown, to the estimated LLD calculated with the standard deviation of the background (σ_b). In this case, the true or limiting mean of the net count, and a substantial fraction of the distribution is below the computed LLD. A resultant net count (N_n) from a typical individual paired observation of background and gross counts (N_b, N_g), which are both well within $\pm\sigma$, is illustrated. If this value and many others less than the LLD are not reported then the distribution of the reported values would grossly distort the true situation given by μ_n and σ_n for the population. This point is demonstrated further in the data of Table 1. Twenty-five net count (N_n) measurement results from a population with a mean of 20 were obtained from paired observations of background (N_b) and gross counts (N_g). The average background of 16 counts was used to estimate the LLD, which has a value of 21.3 or 18.6 counts (depending on the particular equation used to calculate the LLD). The last two columns in the table contain the tabulated results when values less than 21.3 and 18.6 counts are reported as "less than the LLD" (<LLD). In the first case, only 8 of 25

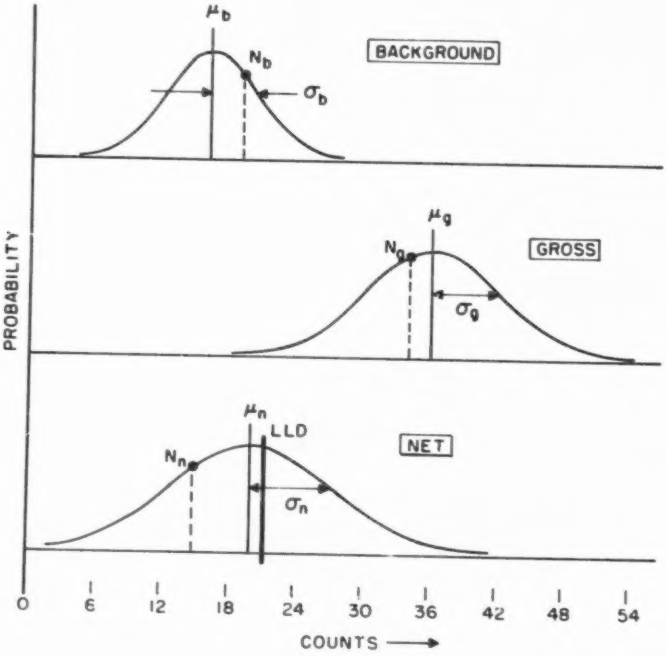

Figure 4

measured results would be specified. How does one average this tabulation? The average of the 8 specified values is 25.4 counts, which may be contrasted to the population mean of 20 counts. If the other 17 "<LLD" values are taken as being equal to the LLD of 21.3 counts (this conservative approach may be the most likely treatment when the tabulated results are ultimately used to make dose assessments), the average of the 25 values becomes 22.6 counts. Even if one invokes the less restrictive LLD of 18.6 counts, 9 of the 25 measured values are "<LLD."

Table 1.

				Distorted N_n Reported Values	
N_b	N_g	N_n	s_n	for LLD=21.3	for LLD=18.6
20	38	18	7.6	<LLD	<LLD
15	36	21	7.1	<LLD	21
18	34	16	7.2	<LLD	<LLD
21	27	6	6.9	<LLD	<LLD
16	36	20	7.2	<LLD	20
17	41	24	7.6	24	24
14	33	19	6.9	<LLD	19
16	44	28	7.7	28	28
17	35	18	7.2	<LLD	<LLD
19	38	19	7.5	<LLD	19
12	32	20	6.6	<LLD	20
15	36	21	7.1	<LLD	21
16	39	23	7.4	23	23
18	34	16	7.2	<LLD	<LLD
23	43	20	8.1	<LLD	20
14	31	17	6.7	<LLD	<LLD
11	28	17	6.2	<LLD	<LLD
16	35	19	7.1	<LLD	19
10	40	30	7.1	30	30
15	37	22	7.2	22	22
22	38	16	7.7	<LLD	<LLD
16	30	14	6.8	<LLD	<LLD
13	37	24	7.1	24	24
17	44	27	7.8	27	27
9	34	25	6.6	25	25
16	36.	20.		25.4 (22.6)	22.6 (21.1)

All values in counts (K = 1).

This distortion of values near the LLD or MDC will always result in a positive bias when one attempts to make realistic estimates over a period of time. The implications can be serious. When making measurements near background levels, one can expect to frequently obtain values that are less than the estimated LLD or MDC. If these values are not recorded and used in making average estimates, then these estimates are always going to be greater than the "true" representation of the environment. Therefore, it is recommended that every measurement result should be recorded and reported directly as found. "Less than the LLD," "not detected," and similar expressions should not be used in reporting data. This does not imply that the activity in the sample is truly less than some absolute level that can be detected. Rather, it merely indicates that this particular measurement resulted in a single value which was less than an estimated LLD or MDC for the measurement procedure.

The MDC is conceptually more complex when the net count is a function of the detector response from two or more radionuclides in the sample. In this situation, the proportionality constant K* cannot relate the net count to the activity of just a single radionuclude. This will not affect the calculation of the LLD, since it is independent of sample conditions and is a function of only the instrument performance (as contained within K) and the uncertainty in the blank background. For many procedures, such as the determination of strontium-89 and strontium-90, with typical samples, this approach has been subject to the criticism that it does not reflect realistic detection capabilities. It is sometimes argued that the LLD must consider that any net count results from contributions from both strontium-89 and strontium-90. This argument is another misapplication of the LLD concept. If it is accepted, then the LLD would no longer be a limit and would be dependent on something other than the instrument background and efficiency characteristics.

The MDC, however, is intended to serve as a practical level that is achievable under a given set of specified measurement conditions, and must consider the effect of multi-components in the sample. One is therefore confronted with a paradox. The MDC should be an a priori estimate, but its determination requires a posteriori knowledge of the amounts of activity in the sample. This dichotomy can be overcome by calculating the MDC for typical sample conditions. This is subject to criticism that some samples may vary substantially from the typical, and that the MDC may then be in considerable error. Without denying this argument, there are two reasons why the effects from such errors are unimportant. First, the MDC is only meant to be an **estimate;** and second, all measurement results should be reported without a comparison to the MDC. As a result, there is no great need for knowing some absolute detection level for every measurement.

The determination of a MDC for activity measurements by gamma-ray spectrometry is a good example of the above described situation. It is complicated in that the background count rate for the same radionuclide may vary from sample to sample. This is because the background is usually the sum of two separate sources of gamma radiation. First, there is the system background radiation for a blank, corresponding to the sample to be measured, as discussed previously. Second, there is Compton-scattered radiation from other higher energy gamma rays in the sample. Thus, it is readily seen that the measurement of blank backgrounds has meaning only for very specific situations; e.g., when only one radionuclide is present in the sample, or when the radionuclide of interest emits the highest energy gamma ray.

For environmental samples, one can assume that almost always two or more gamma-emitting radionuclides will be present in any given sample. Use of the uncertainty in the blank background is appropriate for the LLD, but a more realistic background must be used for calculating a MDC. This sample background will depend upon the relative amounts of other radionuclides that are present in the sample and the energy of each of their gamma rays. Therefore, to satisfy the condition that the MDC be an a priori estimate, it is recommended that it be calculated for each radionuclide from typical spectrum backgrounds for each type of sample.

In summary, the practical significance of the estimated LLD and MDC are only to serve as guideposts or criteria for experiment design, comparison, and optimization purposes, and to serve, for regulatory purposes, as approximate guidelines of minimally acceptable levels that can be practically achieved. As such, all measurement results should be reported directly as obtained, and the estimated LLD or MDC should not be employed to exclude some results from reports. Similarly, the practice of calculating a new LLD or MDC value for every measurement defeats the spirit of the concepts, which is to provide a priori estimates. A posteriori calculations contain no additional information, and are neither technically nor economically justifiable.

The above interpretations place some important restrictions on the use of the LLD or MDC, particularly with respect to satisfying regulatory specifications. The most important restriction is that it is unreasonable for a regulator to establish absolute values for the MDC or LLD for various combinations of radionuclides and type of sample medium, and then expect compliance 100 percent of the time in all situations.

A further restriction arises from the fact that the MDC for a radionuclide may vary from sample to sample depending on the characteristics of the sample. For example, the MDC for strontium-90 is dependent on the amount of strontium-89 which is also present in the sample. Similarly, the MDC for a radionuclide assayed by gamma-ray spectrometry depends upon the number, quantity, and spectral characteristics of other radionuclides which may be present in the sample. It must therefore be recognized that an MDC established for one specific set of conditions may not be applicable for all other conditions. Detection capabilities, notably those specified by the Nuclear Regulatory Commission, are stated to be state-of-the-art for routine environmental measurements. If these state-of-the-art values are established for one set of assumptions (instrument, procedures, and sample variables), then the MDC values should not be expected to be technically achievable unless the assumptions, particularly typical sample composition, are still valid.

The frequent use of a MDC or LLD as a criterion for excluding some results from data reports must not continue. The resulting positive biasing effects of this practice were discussed previously. As a result, it is recommended that all measurement results be reported directly as found; and that "less than MDC" and similar terms never be used.

For some measurements, the reporting of all results will not present a problem. Others, like automated gamma-ray-spectrometer systems, can, however, present a practical problem. Some computer-coupled systems, which routinely test for upwards of 100 or so radionuclides in a system library, would require a data report consisting of a value for every radionuclide in the library. Obviously, such an approach is not reasonable. The current practice of using MDC values to decide which results from the long list will be reported is not the solution. What is needed is a practical approach that avoids the problems inherent in using a preselected exclusion criterion, but at the same time is reasonable. This approach requires that efforts be made to reflect on the purpose of the measurements. Measurement of 100 different radionuclides in a surveillance or monitoring program is neither reasonable nor justifiable. Fewer reliable measurement results are much better than many questionable results. What is needed are more good measurements whose results can be viewed with confidence, not more measurements per se. The criteria for what should be measured (and hence reported) should be based upon what is actually needed for the purpose of environmental radioactivity monitoring and upon the dosimetric significance of the radionuclides. Attempts to measure everything that is technically achievable do not serve anyone (not the laboratories or the public). Laboratories, as well as regulators, must begin to recognize this. An approach that is more reasonsable and justifiable in terms of the dosimetry and purposes of the monitoring must be taken when designing measurement and data reporting programs.

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DISCUSSION

MR. GALPIN: Recently in our quarterly Environmental Radiation Data Report, which goes primarily to the States that participate in our Environmental Radiation Ambient Monitoring System, we went, as you suggest, to this methodology of reporting the numbers, including the negatives, and because of the reasons you suggest, in order to be able to do some decent long-term averaging without having to fudge numbers. There was a contingent of people in the field that just gave us all kinds of hell. "This is ridiculous," "whoever heard of a negative value," "This is going to confuse the public," "The public's going to be down on you," "They will think you are covering things up." I just want to say that it is working, and I have not heard any mass confusion from the public and I do not see many of the problems that people raised and we are going to stick with it.

DR. COLLE: As a matter of fact, I think the fact that ERAMS and the Environmental Radiation Data Report started to report all values has made our task much easier. The only important thing that you have to keep in mind is that when you report a value of - 2, that does not mean that the activity is - 2. It only means that measurement result gave a value which is - 2. That is all it means. If the next one give a value which is + 2 then the average would be zero. That is all it means. We were aware of the ERAMS requirements and I think it was a big help in getting a lot more people to accept it. When we started our committee report had that not been the case, I think we just would have had more of a problem even within our committee.

MR. JONES: I commend your efforts because I am aware of all the difficulties getting reproducible results from laboratories and such but I would like to raise a caution here that I think it may be overkill on that part of the problem and ignoring the real world problems of field work. Our ability to detect radiation is so great that we tend to get tied up with these low levels and ignore the real world problems of differences from place to place. A good example, a few years ago when I was working in a program where we took HeLa measurements in a place in the field and then to get an intercomparison and to check we took spot samples at a few meters square around the area of the detector and we analyzed those to get an idea of how good our data were. We thought we would take some of those samples and examine them a little more carefully. So we picked one that had a beautiful exponential curve for cesium as you go to depth in the soil. We thought we would take that one and take the individual samples and analyze those because that was obviously a good location. The shock that occurred was that starting at one corner the first one had a nice exponential, almost vertical, curve and the next samples went a great deal flatter and the last ones were very flat. So it is obviously a totally inhomogeneous site. So I want to caution that there are some field problems that are so important. The other thing I would like to see you addressing is environmental measurements with something like the TLD. There is no standard that I am aware of. If you build a dosimeter for example that has electronic equilibrium materials for cobalt-60 or cesium-137, it will give different results than somebody who picked the source that you did not. You will see beta particles that will be variable with the height of the sample and the gamma calibration source you are comparing with. There are lots of questions in that area and I think, if nothing else, having some kind of recommendation would at least make us all consistent so that we could intercompare without quite so much uncertainty.

DR. COLLE: I think one of the philosophies one has to keep in mind is the concept that there are things we can currently improve. We can improve data reporting and there are many other things we can improve as well. If we can get our recommended practices firmly established, then we can start marching in other directions. I think a clear direction to move in is the whole question of sampling and I am convinced 100 percent that until you have a good handle on the measurement part of it and on the reporting of measurements so that you can begin to make meaningful comparisons, you are never going to get a handle on the sampling aspect of it. If you can fix up this small area, and although it is just a narrow slice of the whole picture, then I think you can begin to move in other directions.

MR. CRAIG: I am glad to see you presenting these kinds of things and for some of your cohorts in the EPA who have never heard of negative numbers, the Model States Information System which is designed to serve as a data base for the Drinking Water Act has been written in such a fashion that it will not accept negative numbers. I would like to see the NBS and Office Radiation Programs discuss this and convince them that they are going to have a long-term bias and are going to come up with concentrations that are going to give everyone trouble with some new standards.

DR. COLLE: If this is the case, then I would say that there are going to be some problems. Serving on our committee were two EPA representatives; otherwise it strikes me as being matters that are internal to EPA.

MR. WOLF: I think it is extremely important to discuss in some detail what type of environmental quality assurance programs you have, whether you are splitting samples and how many, whether it is 20 percent of the samples that one is collecting and reading. A lot of environmental data are reported without any discussion of the quality control program.

DR. COLLE: A quality control program would literally be used for the most part to evaluate many of the sources of inaccuracy. The Guide contains a detailed example of the assessment and propagation of the uncertainty components for strontium-89 and strontium-90 determinations. Nearly 20 different sources of inaccuracy are identified. Each source has to be evaluated. One of the ways to evaluate them is through various quality assurance programs as well as maintaining inhouse statistical control. Inhouse quality controls and external quality assurance programs by splitting samples and cross-checks will also help evaluate these terms, and over time will also improve the quality of measurements.

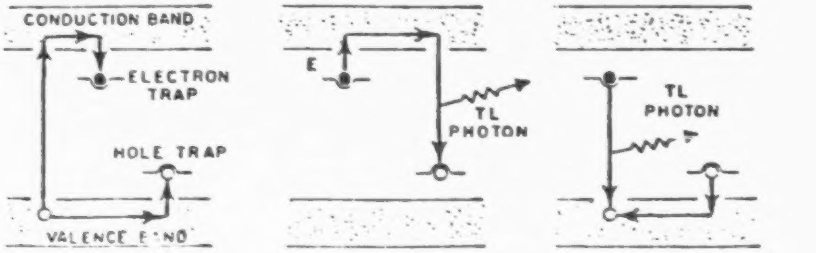
OKLAHOMA TLD

Rita S. Patel, Donald J. Burke, and Robert L. Craig
Oklahoma State Department of Health

Certain materials have the ability to store energy received by irradiation. When these materials are subsequently heated, they release this stored energy in the form of light. This energy release is called thermoluminescent emission.

Ideally the material chosen for dosimetry purposes should respond linearly to absorbed radiation dose. It is also desirable that the material of the dosimeter respond to all types of radiation in a manner equivalent to that of mammalian tissue.

Since lithium fluoride responds in a manner approximately equivalent to tissue and is nearly energy independent, it has an advantage over other thermoluminescent phosphors, and hence was chosen by our department for personnel and environmental dosimetry. Figure 1 depicts the basic thermoluminescent process as explained in "Thermoluminescent Dosimetry" by J.R. Cameron et al. (1). Figure 1a represents a crystal on exposure to ionizing radiation. Ionizing radiation releases an electron from the valance band to the conduction band thus leaving a hole in the valance band. The electron and hole then move through the crystal until they recombine or until they are trapped in the metastable states shown. These metastable states are presumed to be associated with defects in the crystal or impurity sites.



(a) EXPOSURE TO IONIZING RADIATION.

(b) HEATING: ELECTRON TRAP IS LESS STABLE, HOLE TRAP IS THE EMITTING CENTER.

(c) HEATING: HOLE TRAP IS LESS STABLE, ELECTRON TRAP IS THE EMITTING CENTER.

Figure 1

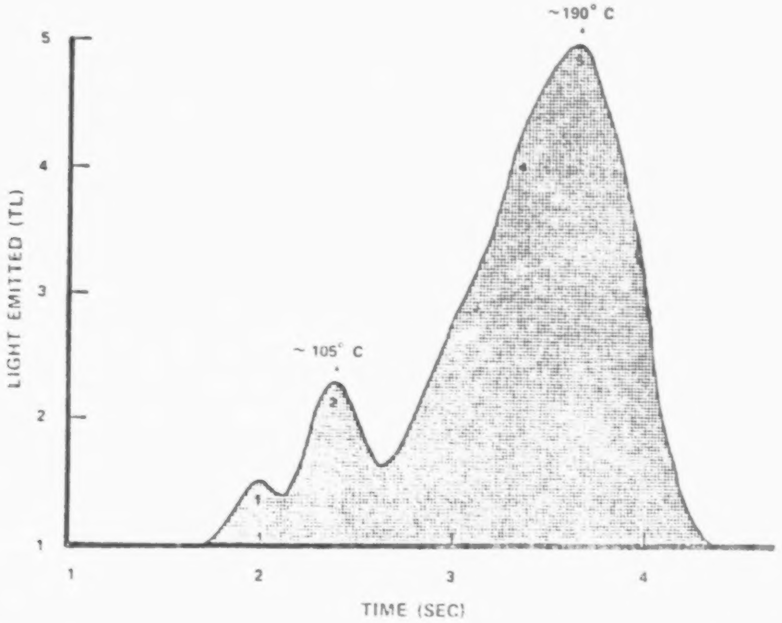
There are two ways by which a thermoluminescent (TL) photon is emitted. When the crystal is heated, sufficient energy may be given to the electron to raise it to the conduction band as seen in (b). This electron may then wander around until it recombines with the trapped hole, at which point a TL photon is emitted. Conversely the hole trap may be less stable than the electron trap as seen in (c). In this case the hole trap receives sufficient energy to wander until it recombines with the trapped electron, and again a TL photon is emitted. On exposure to ionizing radiation many such "trapped" electrons and holes are produced. As the crystal is heated the probability of releasing any particular electron is increased, and at some temperature there is a virtual certainty of its release. Thermoluminescence thus starts out weak, reaches a maximum, and then decreases again to zero.

Pure LiF exhibits relatively little thermoluminescence. Impurities must be present for the appearance of radiation - induced TL. Harshaw Chemical Co., in collaboration with Cameron, developed thermoluminescent-grade LiF, available as TLD-100, TLD-600, and TLD-700. The relative abundances of the isotopes lithium-6 and lithium-7 are shown in Table 1 (1).

Table 1. Relative abundance of lithium isotopes

Isotope	TLD-100 (percent)	TLD-600 (percent)	TLD-700 (percent)
Lithium-6	7.5	95.6	0.01
Lithium-7	92.5	4.4	99.99

TLD-100 containing Li in its natural isotopic ratio, is the least costly and is probably the most widely used TLD phosphor today. When TL is plotted against time or temperature you get what is called a "glow curve." Figure 2 shows a typical glow curve for TLD-100.



Typical glow curve of LiF (TLD-100) after phosphor has been annealed 1 hour at 400° C, read soon after irradiation to 100 R. (Zimmerman *et al.*, 1965.)

Figure 2

After irradiation, peaks 1 through 5 decay at room temperature with the approximate half-lives of 5 minutes, 10 hours, 0.5 years, 7 years and 80 years, respectively. Hence peaks 4 and 5 are the more suitable for dosimetry. Peaks 1, 2, and 3 can be successfully eliminated by proper annealing of the chips.

Oklahoma's TLD Program uses Victoreen's 2800 reader and TLD-100. Three different types of annealing techniques were tested before choosing one for our use.

Method (1) - Victoreen Anneal - (B-anneal described in the manual for the reader). This method consists of cycling each chip through the "LiF - anneal" cycle on the TLD reader, then annealing them at 80 °C for 16 hours (4).

Method (2) - Air Force Anneal - This method consists of a 400 °C anneal for 1 hour with a quick cool to room temperature, then 100 °C anneal for 2 hours with a final 80 °C anneal for 16 hours.

Method (3) - (A composite of two annealing procedures described in the Victoreen Manual) - This method consists of a hot anneal at 400 °C for 5 minutes with a quick cool to room temperature, then 80 °C for 16 hours.

Several experiments were conducted to compare the different annealing techniques.

(1) Fade and Loss of Sensitivity Experiment - This experiment was done to compare fade versus time and loss of sensitivity versus time with three groups of chips annealed by the above three methods.

This experiment involved 150 chips (50 chips per group). Some of the chips were exposed initially to a cesium source for an exposure of 100 mR. Part of these exposed chips were read on the same day. The remaining exposed chips were read at subsequent dates.

The unexposed chips were later exposed at subsequent dates and read out 1 hour after exposure. Other chips remained unexposed and were read for a background reading. Results are shown in Table 2 and 3.

Table 2. Fade

Method	Anneal	Day 0	Day 7	Day 28	Day 92
Method (1)	Victoreen	111.4 (100%)	106.6 95.7%	97.7 87.7%	98.7 88.6%
Method (2)	Air Force	95.9 (100%)	95.1 99.2%	88.2 92.0%	86.9 90.6%
Method (3)	Composite Anneal	105.2 (100%)	104.5 99.3%	97.0 92.2%	94.7 90.0%

Table 3. Loss of sensitivity

Method	Anneal	Day 0	Day 7	Day 28	Day 92
Method (1)	Victoreen	111.4 (100%)	106.6 95.7%	97.7 87.7%	98.7 88.6%
Method (2)	Air Force	95.9 (100%)	95.1 99.2%	88.2 92.0%	86.9 90.6%
Method (3)	Composite Anneal	105.2 (100%)	104.5 99.3%	97.0 92.2%	94.7 90.0%

These results indicated to us that the Air Force Anneal was superior in its loss of sensitivity behavior and as good as or perhaps better than the other two anneals in its fade characteristics.

(2) TLD Background Experiment - In the course of the fade and loss of sensitivity experiment it was noted that the background chips gave unusual readings. These are shown in Table 4.

Table 4. Background chip readings

Method	Anneal type	Day 9[a]	Day 17	Day 37
Method (1)	Victoreen	9,7	4,4	6,6
	average	8	4	6
Method (2)	Air Force	1,1,2	2,1	4,5
	average	1.33	1.5	4.5
Method (3)	Composite Anneal	6,6,4	3,3	5,5
	average	5.33	3	5

[a] Day 9 corresponds to day 0 of Table 2 and 3.

Table 4 shows that two out of the three groups had lower background readings on the second readout (Day 16). However, all the readings did increase on Day 37. Figure 3 is a graph of the above results. Further experimentation confirmed these results.

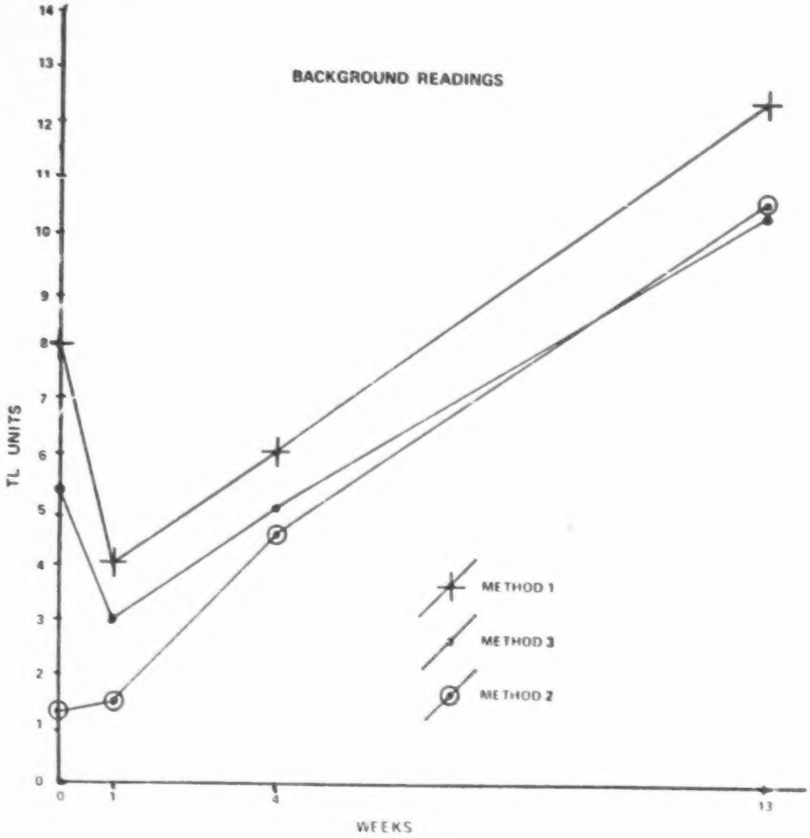


Figure 3

Our conclusion is that the anneal in the reader with nitrogen left the chips vulnerable to triboluminescence effects that were reversed by a few weeks' exposure to air.

The 1 hour anneal at 400 °C in air avoids this problem.

This experiment therefore reinforced our findings that Method (2) was the preferred one for our use.

(3) Reproducibility

The Air Force anneal gave a lower standard deviation for the same chips exposed in the same way 2.75 percent versus 8.08 percent using the Victoreen Anneal. This is probably because of the reproducibility of the cooling of the chips, as each chip is extracted from the pan when the machine anneal is used.

Based on the above results the Air Force Anneal was chosen as the preferred annealing technique by our department. An experiment was then run to measure the minimum detectable radiation using this annealing technique.

In this experiment chips from one batch were divided into 5 groups of 5 chips each.

The 5 groups were exposed and gave readings as shown below.

Table 5

True exposure	O mR	2 mR	5 mR	11 mR	15 mR
Average reading	0.75±0.96	3±0	5.2±0.8	11.3±0.9	15.8±1.0

Figure 4 is a graph representing the above results with 2 standard deviations indicated. It can be seen from the above that results are accurate within approximately 3 mR at extremely low levels of exposure when exposure is in laboratory conditions of temperature, and so forth.

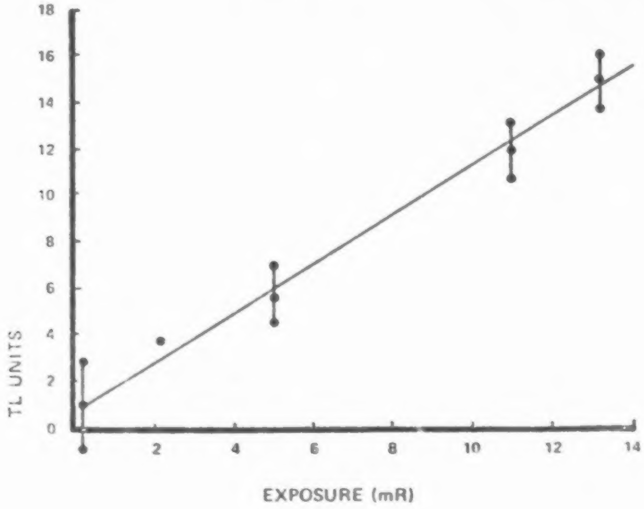
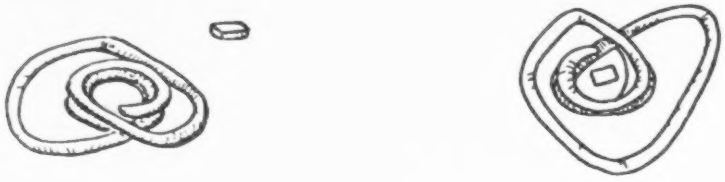


Figure 4

Another test we performed was a chip centering device experiment. On repeated use of the Victoreen 2800 reader the pan on the inside began to corrode. However, a center strip seemed to be darker than either side and hence we assumed the temperature was higher in this middle strip.

Our experiment was done reading chips with and without a centering device. The chips read with a centering device had a lower standard deviation than chips read without a centering device. We therefore decided to institute the use of a chip centering device.

Centering devices are commercially available for LiF glass rods, but not for LiF chips. Therefore, we made a centering device using a paper clip as shown in Figure 5.



OSDH CHIP CENTERING DEVICE

Figure 5

CONCLUSIONS

1. Based on the above experiments, our department chose method 2 (i.e., the 400 °C hot anneal for 1 hour, 100 °C anneal for 2 hours and 80 °C for 16 hours) as the optimum annealing technique.
2. Because of better reproducibility, we use a centering device in our reader.
3. We feel that our results are accurate within approxiamtely 3 mR or 10 percent, whichever is higher.

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STUDY of the LONG-TERM EFFECTS in the BEAGLE from WHOLE BODY EXPOSURE to IONIZING RADIATION-CURRENT FINDINGS

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INTRODUCTION

Ionizing radiation has been known to be associated with a variety of adverse health effects for many years. Most of the information available has been derived from evaluation of human populations or experimental animals exposed to high levels of radiation. The role of relatively low levels of ionizing radiation on disease induction in the human population is poorly established and there is growing concern over the potential effects of both medical and environmental exposures.

A particular concern pertaining to the susceptibility of the human fetus and young children to radiation injury was underscored recently by the events at the Three Mile Island Nuclear Facility in Pennsylvania. It was recommended that pregnant women and young children be evacuated from the area although a general evacuation was not required. With respect to the effects of medical diagnostic radiation exposures a modest amount of information is available. Stewart and Kneale (1) first noted that low-level diagnostic x-ray exposures might be associated with increased cancer risk in children exposed in utero. Such epidemiologic findings have been confirmed by some studies (2,3) but others (4,5) have failed to make similar observations.

A relative paucity of information exists related to the effects of relatively low levels of ionizing radiation delivered during development. Some information is available on effects such as growth retardation, teratogenesis and carcinogenesis (6), but a comprehensive understanding of the effects of age at radiation exposure does not exist.

The Collaborative Radiological Health Laboratory (CRHL) at Colorado State University has been conducting long-term animal experiments for the purpose of determining the lifetime hazards associated with prenatal and early postnatal exposure to ionizing radiation. These are life-span studies of a moderately large and long-lived mammal, the beagle dog, exposed at one of six times during development to discrete doses of external cobalt-60 gamma radiation. The major concern of the experiment is the evaluation of age at exposure as a factor influencing an animal's response to radiation injury. This study is supported in part by United States Public Health Service Contracts FDA 72-302 and 223-76-6002 from the Bureau of Radiological Health, Food and Drug Adminsitration, and this paper is a status report of the ongoing experiments.

MATERIALS AND METHODS

The beagles used in this experiment are derived from a breeding colony at the CRHL. The dogs are housed in outdoor kennels and fed dry kibbled food and water ad lib unless there is a medical reason to change the diet in individual dogs. All dogs are observed daily and given complete annual physical examinations. In case of illness the dogs are given more frequent examinations as required.

In the major long-term experiment, 1,680 dogs received either a single, whole-body exposure to cobalt-60 gamma radiation or a sham-irradiation. All exposures were bilateral for a total of 10 minutes. Dogs were exposed or sham-exposed at 8, 28, or 55 days post coitus (dpc) or 2, 70, or 365 days post partum (dpp). The exposure was either 20 R or 100 R as measured as the midline in-air dose. The detailed procedures for exposures and dosimetry have been reported (7). Table 1 outlines the experimental design for the main long-term study.

Table 1. Experimental design: Long-term effects of whole-body gamma irradiation in beagles

	Esposure (R)					
Age at exposure	0		20		100	
Prenatal exposures	L[a]	S	L	S	L	S
8 dpc[b]	40	20	80	40	80	40
28 dpc	40	20	80	40	80	40
55 dpc	40	20	80	40	80	40
Post-natal exposures						
2 dpp[c]	40	20	80	40	80	40
70 dpp	40	20	--	--	80	40
365 dpp	40	20	--	--	160	80
Number of dogs per level of exposure	240	120	320	160	560	280
Total number of dogs			1,680			

[a] L: Number of dogs scheduled for life-span observation.
S: Number of dogs scheduled for sacrifice at 5, 8, 11 or 14 years of age.
Equal numbers of males and females are present in both L and S groups.

[b] Days post coitus.

[c] Days post partum.

The mean absorbed doses for dogs in the main long-term experiment are given in Table 2. The overall mean dose for dogs exposed at 20 R was 16.3 rads with a range of 15.1 to 17.8 rads for individual animals. The mean dose for dogs exposed at 100 R was 82.6 rads with a range of 75.3 to 93.8 rads. Equal numbers of males and females were used. The dogs were entered into the study over about a 5-year period from 1967 through 1973. Two-thirds of the animals are being maintained for the duration of their natural lives while the remaining one-third are being sacrificed for sequential study at 5, 8, 11, or 14 years of age.

A second experiment has been carried out as a supplement to the main long-term study. In this experiment a wider range of exposures were used to examine delayed effects occurring within a shorter time span than would be possible with the main experiment. It was aniticipated that such effects would serve as a preview of events expected later in life following the smaller exposures of the long-term study. Animals received a single whole body exposure at 8, 28, or 55, dpc, or 2 dpp using exposure conditions similar to those outlined above. Since exposure levels were considerably higher than in the long-term experiment only animals surviving the first 60 days of life were entered into this portion of the experiment. Included were 61 dogs who received 180 to 270 R at 8 dpc, 65 dogs who received 125 to 270 R at 28 dpc, 59 dogs exposed to 220 to 330 R at 55 dpc and 81 dogs who received exposures of 330 to 435 R at 2 dpp. Sixty-four controls were also included. Dogs were assigned to one of four subgroups, respectively, scheduled for sacrifice at 70 days, 2 years, or 4 years of age or available for other testing procedures.

Table 2. Dose statistics: Long-term effects of whole-body gamma irradiation in beagles

Age at exposure	Exposure (R)	
	20	100
8 dpc[b]	15.9	81.6
28 dpc	16.0	80.8
55 dpc	15.6	80.8
2 dpp[c]	17.5	88.3
70 dpp	--	82.6
365 dpp	--	81.2

[a] Days post coitus.

[b] Days post partum.

[c] Mean dose in rads for all dogs exposed in this group.

The circumstances of irradiation, management procedures, ages-at-exposure, and genetic backgrounds of the dogs in both studies described above are identical and data derived from both studies serve as the basis for this report.

A variety of endpoints are being evaluated in the beagles on these experiments including survival, growth and development, physiological functions, and disease incidence patterns. All dogs that die, are euthanatized or are sacrificed at predetermined ages are given complete gross and histological examinations. All diagnoses are made without prior knowledge of experimental grouping. Statistical evaluation of survival and disease incidence data are based on the method of Kaplan and Meier (8).

RESULTS

SURVIVAL

As of December 31, 1978, the dogs in the main long-term experiment ranged from 5.8 to 11.0 years of age. All the exposure times and levels are represented in the youngest through the oldest populations although the control group and the group exposed to 100 R at 365 dpp contain a larger number of older dogs making the oldest dogs in these groups almost a year older than those in any other groups. Table 3 summarizes the current status of the main long-term experiment with respect to survival. Twelve dogs scheduled for irradiation or sham-irradiation died prior to the date set for exposure as shown in Table 3. In the main long-term study at the point when almost all the dogs had reached 6 years of age there were no significant differences in cumulative survival statistics among different irradiation groups and between irradiated and sham-irradiated dogs. Only 28 dogs, including 9 controls, remained alive in the supplementary study as of December 31, 1978.

DENTAL AND SKELETAL DEVELOLPMENT

The number of missing teeth, defined as those that have not erupted by 365 days of age, was evaluated in dogs in both the long-term and supplementary experiments. While the teeth most often found to be absent were upper and lower premolars, evaluation has so far been confined to analysis of a frequency distribution of dogs with any missing teeth. For irradiation at 28 dpc the frequency distribution of dogs with any missing teeth. For irradiation at 28 dpc the frequency of missing teeth was significantly increased for exposures in excess of 125 R. Dogs exposed at 55 dpc and at 2 dpp also had a significant number of missing teeth at exposures of 100 R and above. Dogs exposed at 8 dpc and 70 dpp had no evidence of increased numbers of missing teeth.

Table 3. Current status of long-term experiment: effects of whole body gamma irradiation in beagles[a]

Age at exposure	Exposure (R)	Number of dogs in group	Number died or euthanatized	Number sacrificed	Total number of dogs dead	Percent surviving
Pooled controls	0	360(1)[b]	71	48	119	(67)
8 dpc[c]	20	120	13	12	25	(79)
	100	120	13	12	24	(80)
28 dpc	20	120	22	10	32	(73)
	100	120	11	14	25	(79)
55 dpc	20	120	13	13	26	(78)
	100	120	19	13	32	(73)
2 dpp[d]	20	120	25	14	39	(67)
	100	120	21	12	33	(72)
70 dpp	100	120(2)	20	13	33	(72)
365 dpp	100	240(9)	59	34	93	(61)

[a] As of December 31, 1978.
[b] Total number in group (number that died prior to irradiation or sham-irradiation).
[c] Days post coitus.
[d] Days post partum.

A similar deleterious effect has been seen on the skeletal system of irradiated beagles in both studies. Skeletal growth, as measured by skull size, was evaluated for differences related to sex, age and radiation treatment. Since definite sex and age dependency was found, analysis for radiation effects was tested for each age and sex group independently. A significant decrement in growth of 5 to 6 percent per 100 rads was noted for exposures given at 28 dpc, and 2 to 3 percent for exposures at 55 dpc and 2 dpp. No significant changes in growth were noted for dogs exposed at 8 dpc or 70 dpp. A slight increase in growth was seen in dogs irradiated at 365 dpp, this being statistically significant at the 6 to 7 percent level.

OCULAR EFFECTS

Irradiation during development of the eye, especially the retina, has been found to be associated with developmental abnormalities. Irradiation at 28 dpc, 55 dpc, and 2 dpp has led to retinal dysplasia characterized by focal necrosis of the dysplastic neural retina, which continued for as long as 6 months after irradiation **(9,10)**. Dogs exposed at levels ranging from 10 to 325 R at 2 dpp showed some evidence of necrosis of developing retinal cells although at exposures of 10 to 40 R at 2 pp these changes were minimal, at least when evaluated through 6 months of age. Exposures to 85 R appeared to be near the threshold dose for producing significant dysplasia in dogs exposed at 2 dpp and not all dogs exposed at this level had lesions. In dogs exposed to 125 R or more, the dysplastic lesions ultimately became atrophic. The age at exposure was an important factor in determining the type of lesion seen in that the retina matures centrifugally. Exposures at 28 dpc and 55 dpc tended to cause more severe lesions in the central portion of the retina, while dogs exposed at 2 dpp had more severe lesions in the peripheral retina. The effect of lower level exposures (20 R) at 28 dpc and 55 dpc has not yet been fully evaluated.

RENAL EFFECTS

The canine kidney has been found to have a marked radiosensitivity to radiation injury during development (11-14). Exposure to 270 R or more at either 55 dpc or 2 dpp, when the canine kidney is not fully mature, results in a reduction in renal mass associated with thinning of the renal cortex and failure to form normal numbers of nephrons. Many other nephrons are arrested in their development. These changes are associated with the development of secondary renal lesions characterized by progressive mesangial sclerosis of glomeruli. A large percentage of dogs exposed to 270 R or more in the supplementary study have died in renal failure at relatively early ages. Arrest of nephron development has been seen at exposures as low as 100 R.

Renal function studies indicated that there are significant differences in intracortical blood flow between dogs irradiated at 2 dpp and control dogs reflecting the damage to the cortex. Blood urea nitrogen (BUN) levels have been found to be increased in dogs irradiated at 20 or 100 R at 55 dpc or 2 dpp. It is of interest that this finding was significant only in males and that at higher exposure levels (> 270 R at 55 dpc or 2 dpp) males had a death rate from renal failure 12 times that of females. Another indication of reduced renal function was noted when irradiated dogs with mild renal disease were subjected to unilateral nephrectomy. In nonirradiated dogs BUN levels returned to normal levels within 8 weeks after nephrectomy while several months to more than a year was required in irradiated dogs. Renal clearance of sodium sulfanilate was also reduced in irradiated animals.

NEOPLASIA

In the main long-term experiment one of the major endpoints being evaluated is neoplasia. A listing of the dogs which have died with a malignant neoplaplasm as the major disease process is given in Table 4. Of 31 dogs that died becase of a malignancy, 25 were irradiated. Fifteen of these were exposed to either 20 R or 100 R in the perinatal period, at 55 dpc or 2 dpp. Four of the neoplasms in the perinatally irradiated dogs developed, and were responsible for death, prior to 2 years of age. Of the 25 neoplasms responsible for the death of irradiated dogs, eight were diagnosed as malignant lymphoma. Four dogs with lymphoma were exposed at 55 dpc, two to 20 R, and two to 100 R. Three were exposed to 100 R at 365 dpp and one dog recieved 20 R at 8 dpc.

Many other benign and malignant neoplasms have been diagnosed at biopsy and at necropsy in both irradiated and unirradiated dogs in the main long-term study. While these have not been the cause of death, some may be related to irradiation injury. Testicular neoplasms can be included in this category. Table 5 summarizes the findings with respect to testicular neoplasia in the long-term study. The most striking finding relates to the dogs exposed to 20 or 100 R at 55 dpc. The incidence of testicular neoplasia is unusually high in these groups when compared with the sham-irradiated controls and the mean age at diagnosis is almost 2 years less. This is of even greater significance when it is recalled that the control group contains some of the oldest dogs in the study. Testicular neoplasms are usually found when dogs are sacrificed at predetermined ages or die because of other diseases. On rare occasions a testicle may be removed surgically because of a neoplastic growth. Many dogs that are still alive undoubtedly have undiagnosed testicular neoplasms, which makes the evaluation of true incidence difficult. One can, however, gain a reasonable idea of age-related incidence from the sacrifice series of dogs. In this case, it is highly significant that among the dogs sacrificed at 5 years of age none of 15 sham-irradiated males had testicular neoplasms while four of five males exposed to 100 R at 55 dpc had a total of seven testicular tumors, both interstitial cell and Sertoli cell types.

Table 4. Malignant neoplasia as a cause of death in whole body irradiated beagles[a]

Exposure	Exposure (R)	Number affected	Sex	Ages at death	Type of neoplasm
Pooled Controls	0	6	F	5.9	Adenocarcinoma, undetermined origin
			M,M	7.1,10.1	Pulmonary carciinoma
			F	8.2	Pheochromocytoma
			F	8.4	Mammary carcinoma
			F	8.6	Mammary carcinosarcoma
8 dpc[b]	20	1	M	6.2	Malignant lymphoma
	100	0	-	-	--
28 dpc	20	1	F	6.1	Mast cell sarcoma
	100	0	-		--
55 dpc	20	3	M,M	7.6,90	Malignant lymphoma
			F	7.7	Mammary carcinoma
	100	5	M	0.2	Cerebral astrocytoma
			F,M	1.8,8.4	Malignant lymphoma
			M	7.4	Hemangiosarcoma, skin
			M	7.6	Prostatic carcinoma
2 dpp[c]	20	2	M	1.9	Fibrosarcoma, nasal cavity
			M	7.9	Hermangiosarcoma, spleen
	100	5	F	0.3	Squamous carcinoma, oral
			F	5.9	Ovarian carcinoma
			F	6.8	Cerebellar astrocytoma
			F	8.5	Mast cell sarcoma
			F	8.7	Mammary carcinosarcoma
70 dpp	100	1	F	7.0	Thyroid carcinoma
365 dpp	100	7	M,F,M	5.0,6.2,9.8	Malignant lymphoma
			F	7.5	Urinary bladder carcinoma
			F	8.5	Mammary carcinoma
			M	9.0	Thyroid carcinoma
			M	9.4	Prostatic carcinoma

[a] As of December 31, 1978.
[b] Days post coitus.
[c] Days post partum.

Table 5. Testicular neoplasms in whole body irradiated beagles[a]

Ages at Irradiation	Exposure (R)	No. of males dead/ total no. of males	No. males with tumors	Incidence no. males with tumors/ no. males dead	Mean age of Dogs with tumors (years)
All ages	0	62/180	9	15%	8.51
8 dpc[b]	20	14/ 60	0	--	--
	100	12/ 60	0	--	--
28 dpc	20	15/ 60	0	--	--
	100	11/ 60	1	9%	7.68
55 dpc	20	11/ 60	5	45%	6.85
	100	17/ 60	6	35%	
2 dpp[c]	20	14/ 60	1	7%	8.49
	100	17/ 60	1	6%	
70	100	16/ 60	3	19%	6.82
365 dpp	100	47/120	12	26%	8.78

[a] As of December 31, 1978.
[b] Days post coitus.
[c] Days post partum.

DISCUSSION

It should be emphasized that many of the results reported here are prelimianry in nature. This is especially true with respect to data on neoplasia in the main long-term study. More than 70 percent of the dogs in this experiment were alive as of December 31, 1978, and they ranged from almost 6 to 11 years of age. Thus relatively few dogs had been at risk for as long as 10 or 11 years. Most of the dogs are just now reaching the age at which neoplasia is increasingly frequent. Despite this, several findings of significance have emerged with respect to neoplasia. First, 15 out of 25 irradiated dogs that died due to malignancy were exposed to either 20 or 100 R in the perinatal period; i.e., just before or after birth. Second, four dogs irradiated in the perinatal period died with malignant neoplasms prior to 2 years of age. Third, 8 of the 24 irradiated dogs with fatal neoplasms had one type of tumor, malignant lymphoma, with 4 of these dogs having been exposed just prior to birth. Finally, there has been a higher incidence of testicular neoplasms in relatively young irradiated dogs, mainly in dogs exposed just prior to birth.

Estimates of the incidence of spontaneous tumors in dogs suggest that individually the malignancies seen prior to 2 years of age in our dogs might occur by chance on the order of one in 100,000 to one in 1,000,000 times in animals of comparable ages (15). The finding of four such cases in 1,320 irradiated dogs translates to a rate of 300 in 100,000 dogs. This figure is even more striking when one considers that all four cases were in dogs irradiated in the perinatal period.

Malignant lymphomas are one of the more common neoplasms in the dog and it is not surprising to find them occurring in any canine population. This neoplasm has been reported to occur at a rate of 24 in 100,000 dogs of all breeds (15). At the present time in the 1,320 irradiated dogs in the long-term study, malignant lymphoma has occurred at a rate of 606 in 100,000 dogs, which is more than 20 times higher than what would be expected. This figure is more significant since over 70 percent of the dogs are still at risk for development of this disease. It is also of significance to note that epidemiological studies in man have suggested that the relative risk for childhood cancers, including lymphomas, is increased in persons exposed to prenatal diagnostic radiation (1).

While the development of cancer is of major concern with respect to radiation exposure, other potentially harmful effects should not be overlooked. Decrements in skeletal growth and abnormalities of dental development have been identified in these experiments. While these effects could be significant at high exposure levels it does not appear that they would be of practical significance at low radiation doses, for example, at 10 rads or below. The situation is not quite as clear with respect to the retina and the kidney. There is some evidence of damage to both these tissues when irradiated during their developmental stages even down to 20 R exposures. While much of the data presented was based on relatively high exposure levels (greater than 100 R), further evaluation of dogs exposed at 20 and 100 R may help to determine if there is a significant health hazard associated with prenatal and early postnatal exposures at these relatively low levels. Even mild radiation damage to the kidney which could reduce renal reserve, even if it is not manifested as overt disease, could have serious health effects in the individual with another disease process which also might compromise kidney function.

The experiments reported here were primarily designed to evaluate the effects of a single acute radiation exposure during prenatal or early postnatal life. The potential importance of age at exposure to ionizing radiation in man has been of concern. The current results of this study support such concern and suggest that, for some health effects, the age at exposure is critical and that the perinatal period may well be a time of high radiosensitivity for both injury to late developing organs and carcinogenesis.

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DISCUSSION

MR. STOCKS: Was there anything analogous to the thyroid nodules or anything of that nature that were found?

DR. BENJAMIN: This is something we are working on. We are very concerned with thyroid cancer in our colony and are in the midst of analyzing the effect of the irradiation on both benign and malignant thyroid lesions. We have a complicating factor in that the beagle dog is very susceptible to thyroiditis and hypothyroidism. This is a genetic tendency in the beagle dog and we are beginning to uncover a genetic tendency for thyroid cancer in our beagles as well. Before we can make any kind of statements related to a radiation effect, especially a low-level radiation effect, we have to separate out the genetic effect that we have. We are working on this and there does appear to be some suggestion that there is a radiation effect there, but it is just too early to confirm.

MR. NEILL: The observed incidence of some of the bioeffects that you have described here appears to be highest in the group that was irradiated late in the prenatal period. That brings up the question of the groups that are irradiated just after conception and the 8-day post coital irradiation. Would you speculate whether there is less radiosensitivity in the animals irradiated shortly after conception or would there be a higher abortion rate within that group therefore you are not seeing those effects?

DR. BENJAMIN: The levels that were used here, both the 20 R and 100 R exposure, had been shown by the initial studies to be associated with less than a 5-percent reduction in fetal viability. Those levels should not have caused significant prenatal death, even though there obviously was probably some. In the 8-day post coitus time period, the embryo is in a morula stage. You would expect that if there is going to be a radiation effect, it will be an all or none effect; that you will either kill the embryos or you will not. But again, the radiation levels used were such that the litter sizes and so forth in the animals exposed at 8 days were no different then those exposed at any other time.

MR. NEILL: One of the interesting practical consequences if those results were continually borne out, might be that if a woman requires x rays during her pregnancy then the recomendation would be to have them as soon after conception as possible and not late in the period.

DR. BENJAMIN: I can see that as a possibility, but I certainly would not recommend that at this point.

MR. NEILL: What are you doing in worrying about the fact that a cobalt-60 is a 1.25 MeV gamma and the analog of those exposures to keV level energies?

DR. BENJAMIN: Again I reemphasize the fact that we are not trying to mimic the human situation. The experiment is set up to look at age-related sensitivity and that does not say that the exact type of result would take place if one used a different type of exposure or lower keV. The main thing is to look at the effective age at exposure. As long as we keep the parameters identical within the experiments, then I think the results are valid for what we are trying to do. We are not trying to mimic the human situation; that is an impossible thing to do. As soon as you move away from the human in any type of experiment, there is always the argument that you are no longer dealing with the human and therefore species differences take over.

MR. GALPIN: I know that in biological experimentation 100 rems is a low dose and 20 is a very low dose. However, when the general public gets that number tied up you know it means the same to them as anything down to 5 mrem or 25 mrem and I wonder if biologists in experimentation are considering any other nomenclature, for low-level radiation for public exposure is really a very high level.

DR. BENJAMIN: I think your point is well taken. I think it is a good question and it is one that is going to become more important as the public becomes more aware of what radiation exposure levels really are. Originally this study was set up and the title of it was Exposure to Low-Level Radiation. That was almost 20 years ago and at that time the advisory group did not even want to include the 20 rem exposure group in there because it was felt no effects would be seen. Some of you may have noticed that there were 2 groups missing from that experimental design; the 20 rem exposures at 3 months of age and at a year of age. Well, that was a compromise to reduce the cost of the experiment. They agreed to put in at least the 20 rem exposures at the prenatal and early post-natal time. In retrospect, we would love to go back and have those groups now because they could have been among the most important blocks in this experiment. But I think your point is well taken and I will certainly consider that for future reference. The 16-rad range is not out of the realm of what can be delivered in diagnostic radiology. It is high, but people are still being exposed to doses in that range. So it is still not out of the realm of what people do get.

MR. BURKE: What was the dose rate?

DR. BENJAMIN: The original experiment was set up and the argument went: Do we go with a single dose rate at different times of exposure or two dose rates? That was 20 years ago when people were not quite so concerned about dose rates as they are now. The dose rate was different in the two exposure groups. The 20 rem group was an exposure rate of 2 rem/min, the 100 rem group was an exposure of 10 rem/min. So they both got 10 minute exposures. We are not trying to calculate a dose response curve and are looking at relative age sensitivity. As long as those parameters are kept the same and one looks at 20 rem at 55 days post coitus and 20 rem 2 days post partum, you can make those comparisons. Those are a couple of problems we have to deal with in terms of analyzing the data.

MR. SHREVE: With the intrigue of the results and the impact, what plans if any are there for filling in some of the holes that you now recognize as holes. It would seem that with the big furor over radiation, you ought to have some ready money available. You just have to take another section of land and build a kennel.

DR. BENJAMIN: A study like this extends over a period of 25 to 30 years and we are now 12 years into the main experiment. This would put this study another 12 years down the road, or more than that if we were to start filling some of these blocks. That is not a good reason not to do it, however, that is a reason that the funding agencies are not very willing to do it. The cost of a beagle-dog study is enormous. This study has already cost almost

$20 million over its lifetime and it is going to continue to be expensive. Simply, if we could get the money, I would love to expand this study into some of the areas we have not yet touched, but very honestly I do not see the money coming from anywhere because it is not available at the kind of levels we really need.

DR. NEILL: It is not generally recognized that this project represents about 25 to 26 percent of the total contract money of the BRH, so it is a major commitment.

DR. BENJAMIN: I am not knocking BRH, because they have supported this study fantastically to get as far as we have gotten; it is simply a matter of finances. This is a terribly expensive type of experiment.

MR. SHREVE: I remember the early days because much of this was done in Academia of course, you are from that camp. You had to publish or perish and everybody was interested in acute effects and many of us agitated in the late 1950's and early 1960's to try to turn this around and get some dedicated researchers well-funded to do these things.

BEST DOCUMENT AVAILABLE

IS THERE an ENVIRONMENTAL RADIOFREQUENCY RADIATION PROBLEM?

David E. Janes, Jr.
Office of Radiation Programs, EPA

INTRODUCTION

The question that the program committee has posed for us this afternoon is, "is there an environmental radiofrequency radiation problem." Well, if a growing public concern about exposure to radiowaves including microwaves is a problem, then there is a problem. Figure 1 is a partial tabulation of the inquiries for which we prepared written responses in 1978. I am sure your experience is similar and that is one of the reasons for the inclusion of this topic on the program. As you can see the public's interest ranges from the low power radars used for measuring the speed of vehicles to high voltage power lines and includes radio and television broadcast systems and the larger radar systems.

INQUIRIES CONCERNING ELECTROMAGNETIC
ENVIRONMENTS RECEIVED BY ORP IN 1978

RADIOFREQUENCY ENVIRONMENTS	56
General (34)	
Sutro Tower (3)	
Satellite Communications (3)	
Microwave Towers (16)	
RADAR	20
PAVE PAWS (14)	
Police Traffic (4)	
Other (2)	
OTHER SOURCES	16
BIOLOGICAL EFFECTS	12
GENERAL INFORMATION	32
HIGH VOLTAGE TRANSMISSION	23
REPRINT REQUESTS	146
High Voltage (79)	
All Otners (67)	

Figure 1

The reasons for this concern are complex and I will not attempt to analyze them here other than to mention some of the contributing factors which include:

1. The negative connotation of the word "radiation" and a tendency to associate ionizing radiation effects with nonionizing radiation.

2. The large difference between exposure standards used in the East and the West, though these differences are often more apparent than real in actual practice.

3. The multiple uses of the term "low-level effects." In the United States biological effects studies that use exposure rates between 1 and 10 milliwatts per square centimeter are called low level studies. The Soviets consider studies at rates below one-half a milliwatt per square centimeter to be low level. We talk about exposure rates in the general environment, which are usually in the sub-microwatt per square centimeter range, as being very low levels. All of these meanings get lumped under the term, low level, without a general appreciation that the exposure rates we are talking about may differ by more than a thousand fold.

4. Then there is the tendency of some to use the apparent uncertainties about effects or hazards to block the construction of sources, when it appears that the real objection is to the visual impact of the source or perhaps a perceived reduction in property values. These factors are often magnified and distorted when they are presented in the media. Headlines cannot help but create apprehension in the reader. What I would like to do today is review with you what we know about the radiowave and microwave environment so that we have the background to determine where this public apprehension or concern is justified.

I will begin with a very brief discussion of the quantities and units we will use to specify exposure rate, define two radiowave environments (the general and the specific source) and give the results of some measurements in these two environments. During this discussion, I will also briefly discuss some of the instruments that are used to make measurements in these two radiowave environments. Then, because of a last minute request, and time permitting, I will briefly discuss extra-high-voltage transmission lines, though they are not really radiowave sources.

QUANTITIES AND UNITS

The commonly used quantity for the rate of exposure to radiowaves is the area power density. The internationally accepted unit is the watt per square meter (W/m^2), but for historical reasons exposure rate is often expressed in terms of milliwatts (mW) or microwatts per square centimeter (μW/cm^2); i.e., 1 W/m^2 = 0.1 mW/cm^2 = 100 μW/cm^2. Radiowaves are electromagnetic waves and they have both an electric and a magnetic component. The electric component, E, is called the electric field strength and its units are volts per meter (V/m). The magnetic component, H, is called the magnetic field strength and its units are amperes per meter (A/m). For a point source or for distances far enough from an extended source that it can be treated as point source, the power density is proportional to the square of either the electric or magnetic field strength. These quantities are illustrated in Figure 2. The power density is a measure of the rate at

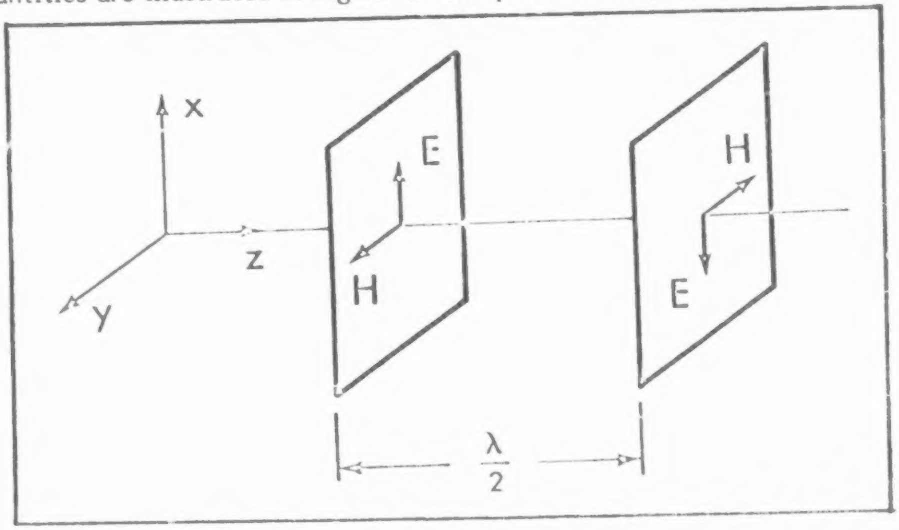

Figure 2

which energy crosses a unit area and it is represented by a vector that lies along the z-axis. For fields from point sources, the electric and magnetic field vectors lie in a plane perpendicular to the direction of propagation. We recall that for electromagnetic waves the product of the frequency and the wavelength is equal to the speed of light. Frequency is specified in cycles per second or hertz. The radiofrequency spectrum extends from 1000 hertz (or 1 kilohertz) to 300 billion hertz, and this corresponds to a wavelength range of 300,000 meters to 1 millimeter. Microwaves are that portion of the radiofrequency spectrum that lies above 300 megahertz; that is, microwaves are radiowaves with wavelengths between 1 meter and 1 millimeter. Most of the sources of interest fall into a frequency range that is conveniently described in terms of megahertz.

RADIOFREQUENCY ENVIRONMENTS

The entire population is exposed to radiowaves from a variety of sources. Examples include: radio and television broadcast systems, radar, citizen band radio, microwave relay links, medical diathermy unmits, heat sealers, and microwave ovens.

It is convenient to define two kinds of exposure. One occurs at distances far from individual sources, and the exposure is due to the superposition of the fields from many sources operating at different frequencies; we will call this the general radiofrequency environment. The other kind of exposure occurs so close to a source that the radiofrequency environment is dominated by the source (or sources) at that location; we will call this the specific source environment.

THE GENERAL RADIOFREQUENCY ENVIRONMENT

The general radiofrequency environment is composed of the fields from many sources, operating on many different frequencies and its characterization requires the use of sophisticated instrumentation.

BROADCAST SOURCES

The general radiofrequency environment is dominated by radio and television broadcast transmissions. The frequency bands of the principal contributors are shown in Table 1. Since 1975 we have been making measurements in these bands using a system especially designed for this purpose. The system consists essentially of the antennas shown in this

Table 1. Frequency bands of principal contributors to radiofrequency

Frequency (MHz)	Use	Antenna
0-2	VLF Communications and AM Standard Broadcast	Active Vertical Monopole
54-88	Low VHF Television Broadcast	Two Horizontal Orthogonal Dipoles
88-108	FM Broadcast	Three Orthogonal Dipoles
150-162	VHF Land Mobile	Vertical Coaxial Dipole
174-216	High VHF Television Broadcast	Two Horizontal Orthogonal Dipoles
450-470	UHF Land Mobile	Vertical Coaxial Dipole
470-806	UHF Television Broadcast	Horizontal Polarized Directional Log Periodic

table. The signals from these antennas are fed to a scanning radio receiver called a spectrum analyzer (Fig. 3) that measures the electric field strength as a function of frequency, and the field strength data is sampled, processed, and stored by a small computer. To provide mobility, the entire system is housed in a van (Fig. 4) equipped with its own power source. This figure shows the van, with the orthogonal antenna used for measurements in the FM-radio band. The equipment inside the van is illustrated in Figure 5. The radiofrequency detection equipment is in the rack to the left and the computer is behind the

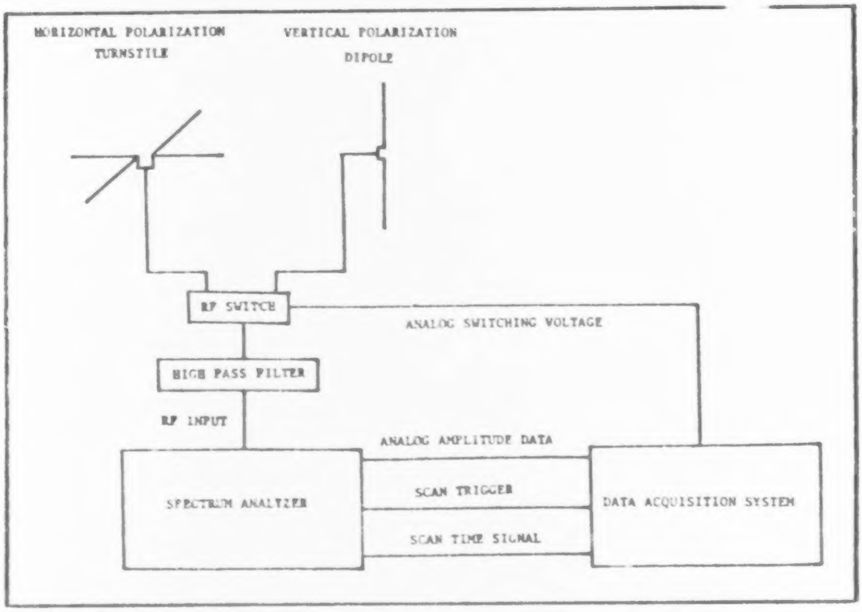
HORIZONTAL POLARIZATION
TURNSTILE
VERTICAL POLARIZATION
DIPOLE
RF SWITCH
ANALOG SWITCHING VOLTAGE
HIGH PASS FILTER
RF INPUT
ANALOG AMPLITUDE DATA
SPECTRUM ANALYZER
SCAN TRIGGER
SCAN TIME SIGNAL
DATA ACQUISITION SYSTEM

Figure 3. Block diagram of measurement system

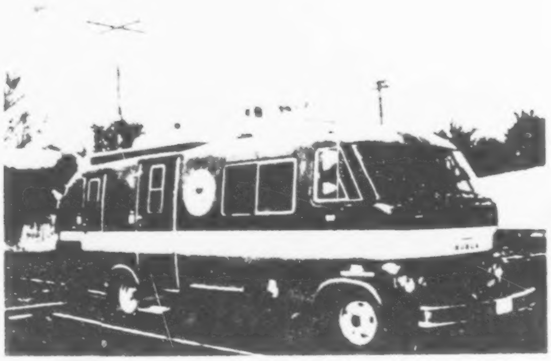

Figure 4. Exterior of measurements van showing FM antenna

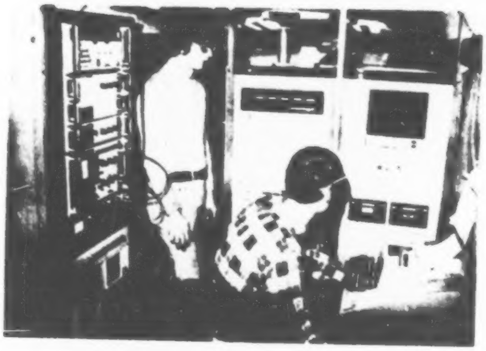

Figure 5. Radiofrequency detection equipment and minicomputer inside van

operators. After being processed, the data are displayed on the computer's cathode-ray-tube. Typical data for one of the television bands are shown in Figure 6. The vertical scale is electric field strength in logarithmic units (decibels above one microvolt per meter) and the horizontal scale is frequency in megahertz. The three-peaked signals for two television signals are present. The peaks within each envelope correspond to the visual, chromance sub-carrier, and audio signals, respectively. Similar data for the FM-radio band are shown in Figure 7. The 15 signals on this display serve to illustrate the multi-source and multi-frequency nature of what we are calling the general radiofrequency environment.

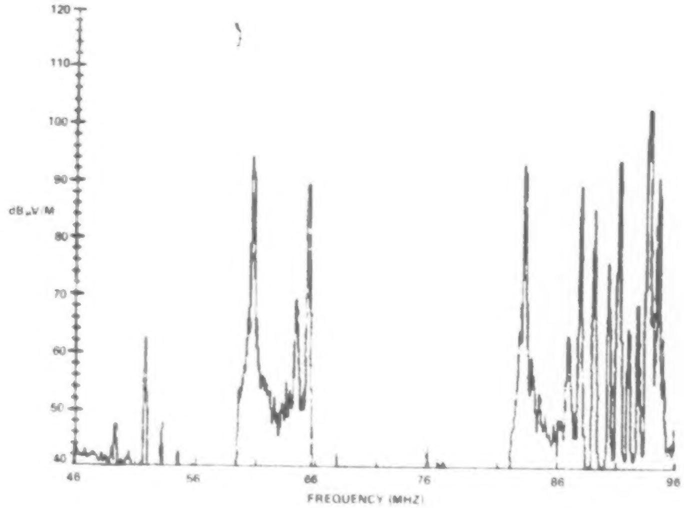

Figure 6. The lower VHF television band (Channels 2-6) at a site in Philadelphia. The vertical scale (ordinate) is in decibels above 1 microvolt per meter (dBμV/m).

These types of measurements have been made at 486 sites distributed among 15 cities with a total population of over 44 million. Some of the data are summarized in Figure 8. Here we have plotted the cumulative fraction of the number of sites on the vertical axis against the logarithm of the power density on the horizontal axis. Do not attempt to read the scales. I have included this figure to make some points about the relative contributions of the bands and I will give you some results on exposure-rates in a moment. The solid

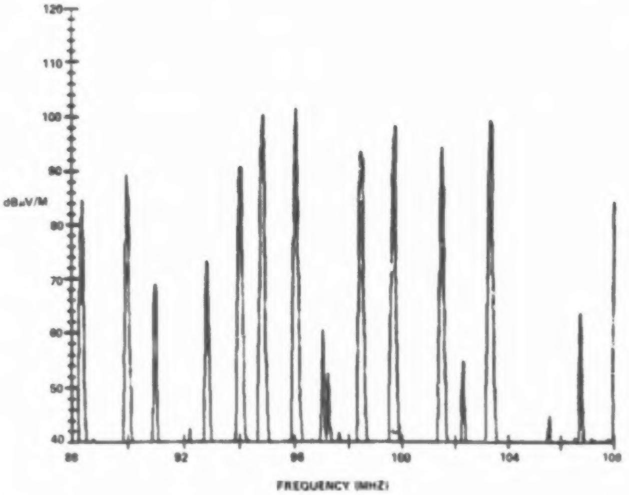

Figure 7. The FM radio band at a site in Atlanta. The vertical scale (ordinate) is in decibels above 1 microvolt per meter (dBμV/m).

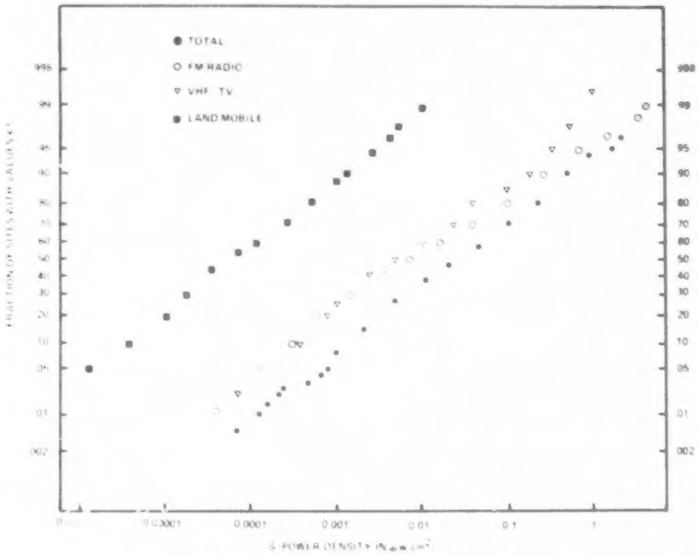

Figure 8. Distribution of power densities at 193 measurement sites (for clarity, not all points are plotted).

circles represent the total power density, the open circles the FM-radio band, the inverted triangles the VHF-TV band and the solid squares the land mobile bands. The UHF-TV data has been omitted for clarity but its contribution is about equal to that of the VHF bands. Note that the FM-band contributes the most to the total power density, especially at the higher values. Note also, since this is a logarithmic display, that the land mobile bands make an almost negligible contribution to the total power density for the general radiofrequency environment. Citizen band radio makes an even smaller contribution. However, we shall see later that the specific source environments of these personal radio devices may not be negligible.

We have taken the results of these measurements, the 1970 census data, and a propagation model, and have calculated estimates of population exposure-rate (Table 2). Note that among the cities the median values differ by about an order of magnitude; from 0.002 microwatts per square centimeter in Chicago and San Francisco to about 0.02 in Boston and Portland. Also note that the percent of the population exposed to less than 1 microwatt per square centimeter is fairly uniform from one city to another; i.e., between 97 and 99 percent. The median value for all cities taken together is 0.005 microwatts per square centimeter. Table 3 combines all of the data and shows that exposure rates are strongly biased to lower values. Note that 50 percent lie below 0.005, 90 percent lie below 05, and almost 99 percent lie below 0.5 microwatts per square centimeter. These estimates do not include contributions from the AM band. The absorption of energy by humans at AM frequencies (0.535-1.605 MHz) is orders of magnitude less than at FM and TV frequencies (54-890 MHz). If one were to include the contribution of AM-radio, it would not double the power density figures given here. These exposure rate estimates, which are based on census data, apply to continuous exposure of people where they live. They do not account for population mobility, for exposures at heights greater than 6 meters (20 ft), the attenuation of signals by buildings, or for periods of time when sources are not transmitting.

Table 2. Population exposure in 15 U.S. cities
(54-900 MHz)

City	Median exposure ($\mu W/cm^2$)	Percent exposed ≤ 1 $\mu W/cm^2$
Boston	0.018	98.50
Atlanta	0.016	99.20
Miami	0.0070	98.20
Philadelphia	0.0070	99.87
New York	0.0022	99.60
Chicago	0.0020	99.60
Washington	0.009	97.20
Las Vegas	0.012	99.10
San Diego	0.010	99.85
Portland	0.020	99.70
Houston	0.011	99.99
Los Angeles	0.0048	99.90
Denver	0.0074	99.85
Seattle	0.0071	99.81
San Francisco	0.002	97.66
All Cities	0.0048	99.44

OTHER SOURCES

Both low- and high-power sources that operate at frequencies outside of the broadcast bands do not contribute very much to the general radiofrequency environment, though the contribution of the higher powered devices to specific source environments may be large. Low-power devices include: microwave relay links, personal radios such as radio telephones and citizens band, and the traffic radars used by law enforcement agencies for measuring the speed of vehicles. High-power sources include satellite communication systems, military acquisition and tracking radars, and civilian air traffic control and air route surveillance radars. All of these high powered systems use highly directive antennas, their beams have small cross-sectional areas, and only a small volume of space is illuminated at any instant. For many of these systems the antenna is high above ground or is pointed 2 to 3

Table 3. Cumulative population exposure for 15 cities (54-900 MHz)

Power density ($\mu W/cm^2$)	Cumulative percent* of population
0.002	19.5
0.005	49.5
0.01	68.7
0.02	82.4
0.05	91.4
0.1	94.7
0.2	97.
0.5	98.8
1.0	99.4

*For example, 19.5% are exposed to levels less than 0.002 $\mu W/cm^2$, 68.7% are exposed to levels less than 0.01 $\mu W/cm^2$, etc.

degrees above the horizon, thereby making exposure to the main beam improbable. Most radar systems rotate, which further reduces the average exposure. The contribution of radars to the general radiofrequency environment in one large urban area is summarized in Table 4. The largest value of power density, 0.001 microwatts per square centimeter is less than the median value for the broadcast frequency bands. In concluding our discussion of the general radiofrequency environment, we note that power densities are very low. Certainly well below the 10,000 microwatt per square centimeter voluntary ANSI standard used to control occupational exposures and for over 99 percent of the population less than those of the Soviet Union, the world's most conservative standards, of 1 microwatt per square centimeter for frequencies below 300 megahertz and 5 microwatts per square centimeter for frequencies above 300 megahertz.

Table 4. Typical urban radar environments

Location	Number of Sources	Average Power Density ($\mu W/cm^2$)
Mt. Diablo	8	2.6×10^{-5}
Palo Alto	10	2.7×10^{-4}
Bernal Heights	10	1.1×10^{-3}

SPECIFIC SOURCE ENVIRONMENTS

Now I would like to turn to the radiofrequency environments produced in the immediate vicinity of some specific sources. These environments, either because of source power or proximity, are usually dominated by the field or a single source operating at a fixed or limited range of frequencies. The measurement techniques used in the general radiofrequency environment can also be applied to specific sources. However, hand-held portable instruments are used more commonly. Some typical instruments are illustrated in Figure 9. To my knowledge there is no single, portable instrument that covers the entire frequency range of interest. Almost all of the commonly used instruments are capable of measuring all three spatial components of either the electric or magnetic field. In the far-field, the power density is proportional to either of these squared quantities so that the meter face is often labelled in power density. For frequencies above 300 MHz an electric field sensor is usually used. For frequencies below 300 MHz both electric and magnetic field sensors are used. It is important to note that for frequencies below about 300 MHz, both the magnetic and electric fields should be measured if one is closer than a few wavelengths to the source. Most of these portable instruments have minimum sensitivities of about 20 microwatts per square centimeter and while they can be used to analyze some specific source environments they do not have enough sensitivity to measure the sub-microwatt levels found in the general radiofrequency environment.

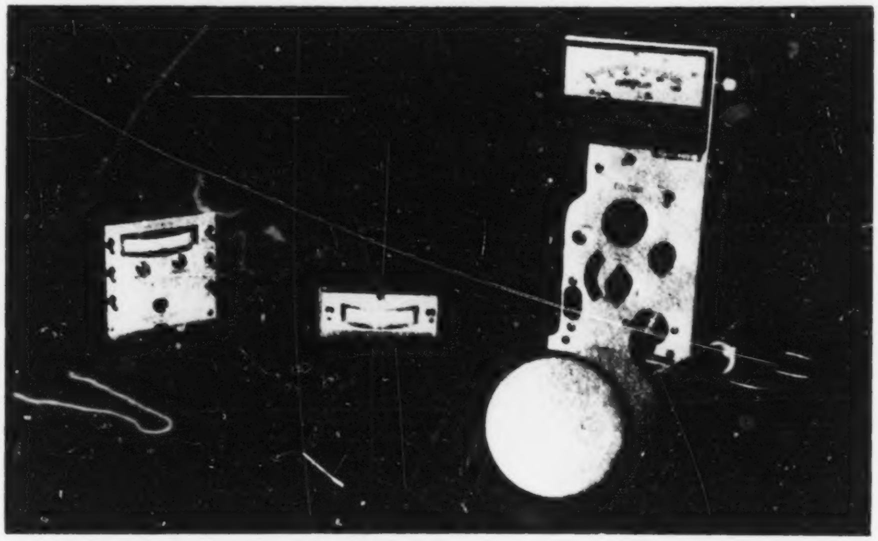

Figure 9. Electric and magnetic field measuring instruments.

BROADCAST SOURCES

The antennas used for FM and VHF- and UHF-TV broadcasting are highly directive. With antenna patterns such as this, levels at high elevations close to the source can be considerably greater than those found at ground level. Measurements have been made in tall buildings that either support broadcast antennas or are within a city block or so of another tall building that supports a broadcast antenna. Table 5 gives the results of measurements in two buildings located very close to FM broadcast antennas. Note, for the first building how the power density increases with height just as would be predicted from antenna patterns. Note also the inversion with height in the second building where windows above the 10th floor were equipped with reflective film to reduce solar heat loads. These transparent metallized films also attenuate radiowaves. The rest of our building measurements are summarized in Table 6. Note that values decrease as one moves away from windows, that both FM and TV can contribute depending on what sources are close. Exposure rates in buildings close to broadcast antennas range from less than 1 $\mu W/cm^2$ to 97 $\mu W/cm^2$ at an unshielded location on the roof of one building. Note that two things are required to obtain these higher levels, high elevation and close proximity (a few hundred feet or less) to an antenna of a high-power source. The upper floors of tall buildings located far from broadcast antennas are not exposed to levels that differ significantly (factors of 10) from those found near the ground at equivalent distances.

Figure 10 shows an 8-element FM broadcast antenna. Tower climbers who perform maintenance, painting, adjustments, and so forth, on broadcast towers may be exposed to local fields near the elements that are in excess of 100 milliwatts per square centimeter. Power densities near the bases of FM towers are typically 1 to 10 microwatts per square centimeter. However, some FM antennas have a grating lobe that is coaxial with the tower in addition to the main lobe directed toward the horizon (Fig. 11). Fields of 100 to 350 microwatts per square cemtimeter have been measured in areas that are accessible to transient foot traffic. These levels fall off rapidly with distance from the antenna tower, but levels near a few residences may range from 50 to 100 $\mu W/cm^2$. In a single unusual case, fields near the base of an FM antenna tower ranged between 1000-7000 $\mu W/cm^2$. Exposures, in open areas, i.e., not close to conducting structures, did not exceed 2000 $\mu W/cm^2$.

(Figure 10 not available)

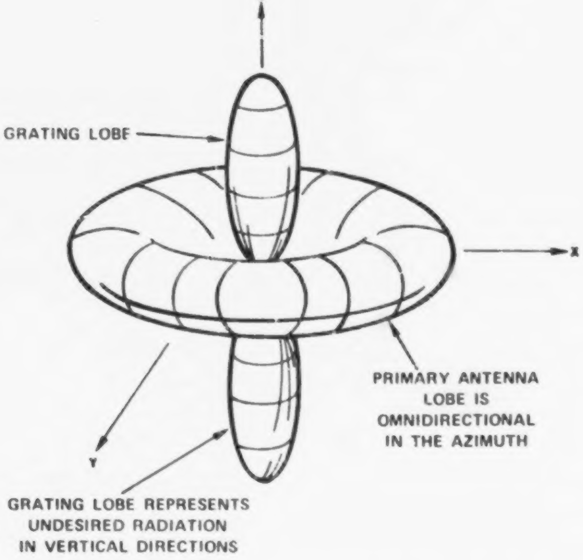
Z
GRATING LOBE
X
PRIMARY ANTENNA LOBE IS OMNIDIRECTIONAL IN THE AZIMUTH
Y
GRATING LOBE REPRESENTS UNDESIRED RADIATION IN VERTICAL DIRECTIONS

Figure 11. Pictorial representation of the grating lobes of some types of FM antennas.

SATELLITE COMMUNICATIONS AND RADAR SYSTEMS

Two other high-power sources are some of the satellite communications systems and the radars used in air route surveillance. Satellite communications systems are continuous wave sources and radars are usually pulsed modulated. A study done by the Electromagnetic Compatibility Analysis Center in 1972 identified 223 continuous wave sources with effective radiated powers greater than 1 megawatt and 375 pulsed sources with peak effective radiated powers of 10 gigawatts or greater. The power density in the main beam of these systems can be greater than 10 milliwatts per square centimeter. However, as discussed above, the probability of being illuminated by the main beam of one of these sources is quite small. Persons who live or work near high power sources, e.g., near airports or military bases, may be exposed to sidelobe or secondary radiation from systems that have stationary or slowly moving antennas as well as from many types of radars with rapidly moving antennas. Calculated exposures fall into the range of 10 to 100 microwatts per square centimeter at distances up to one-half mile from some of these systems. For high-power radars, a combination of mitigating factors, i.e., beam motion and antenna elevation angle, make it unlikely that power densities will exceed 50 microwatts per square centimeter at distances greater than one-half mile from the source, at least in locations that are accessible to people.

LOW-POWER RADAR

Two other radars that are in common use are weather radar in aircraft and navigational radar on small boats. Normally, aircraft radar are not operated on the ground. Power densities for a number of radar-aircraft combinations were less than 10,000 microwatts per square centimeter everywhere except directly on the surface of the radome housing one system for the 5 systems studied. Values were less than 1,000 microwatts per square centimeter at distances greater than 3.5 meters (11.5 feet). For marine radars the computed average power density for any of the 6 units measured by the Bureau of Radiological Health that were studied was less than 50 microwatts per square centimeter at the antenna's turning circle radius. One of the units has an option for sector scanning, and when operating in this mode the maximum power density was about 250 microwatts per square centimeter.

The radars used for measuring the speed of vehicles have transmitter powers of about 100 milliwatts (0.1 watts). These devices are either hand-held or vehicle mounted. They are continuous wave rather than pulse modulated and determine speed from the Doppler frequency shifts of the returned signal. The maximum calculated power density for typical devices ranges from 170 to 400 microwatts per square centimeter at the face of the device and decreases to less than 24 microwatts per square centimeter and 0.2 microwatts per square centimeter at distances of 3 meters and 30 meters, respectively.

MICROWAVE RELAY LINKS

Figure 12 is a tower upon which are mounted several microwave communications antennas. Currently these devices are causing much more public apprehension and concern than the exposure rates they produce would warrant. In 1969 there were over 71,000 microwave towers and the number has increased since then. This high visibility may account for part of the public's interest. Microwave relay links used for long distance communications have transmitter powers that usually are 5 watts or less. The maximum power density is calculated to be about 700 microwatts per square centimeter in the beam; except for service personnel these fields do not occur in accessible locations. Maximum values at ground level are calculated to be less than 10 microwatt per square centimeter and measurements indicate that the maximum fields are much less.

(Figure 12 not available)

PERSONAL RADIOS

Most of the information for the specific source environments produced by personal radio devices is for systems mounted on vehicles or for hand-held walkie-talkies. Interpretation of this data is difficult because most of the measurements are made in the near-field and these fields are not uniform over volumes comparable to the size of humans. The absorption patterns for these complex near-fields may differ appreciably from those produced by far-field whole-body exposures; the absorption may be higher or lower and the sites of maximum absorption may be different. Furthermore, the operation of these devices is intermittent and duty factors are variable, which complicates the determination of average exposure. Because measurements are made in the near-field, the measured values are expressed in volts per meter. Let us recall that power density is simply related to the electric and magnetic fields only in the far-field. To obtain power density in the near-field, the magnetic field must also be known. Some authors have defined an "equivalent" free field power density by assuming the impedance value for free space and calculating the power density, S, according to the equation $S=E^2/(377) = 377\ H^2$. However, when used in this manner "equivalent" does not necessarily mean an equivalent heating power density. If one ignores this complication and performs the calculation anyway, then 10,000 microwatts per square centimeter is "equivalent" with equivalent in quotes, to 200 volts per meter. The available data is summarized in Table 7. The values range from a few volts per meter to 1,350 volts per meter.

Table 7. Electric field strength in and around radio equipped vehicles

Frequency (MHz)	Power (watts)	Vehicle type	Field (V/m)	Dist. (m)
27.075	4	Sedan	2-7	1
27.12	4	Sedan	225-1350	0.05
27.12	4	Sedan	100-610	0.13
27.12	4	Sedan	21-60	0.6
27.61	80	Sedan	21-251	-
40.27	110	Sedan	10-190	-
40.27	110	Sedan	75-368	-
40.27	110	Semi	5-475	-
41.31	100	Comp.	5-106	-
41.31	100	Pickup	7-165	-
162.475	110	Sedan	8-201	-
164.45	60	Sedan	5-52	-
164.45	60	S.Wag.	5-64	-
164.45	60	Van	5-95	-

Only minimal data is available for the fields produced by hand-held walkie-talkies (Fig. 13). In one study electric fields 12 cm from a 2.5 watt hand-held unit operating at 27.12 MHz were measured to be as much as 205 V/m, which has an "equivalent" power density of 11 milliwatts per square centimeter. The measured magnetic field was 0.9 A/m which is "equivalent" to 31 milliwatts per square centimeter. Note the complexity of the field and that the maxima for the electric and magnetic fields occur at different points. Maximum fields of 200 nanojoules per cubic meter (212 V/m or 11.9 milliwatts per square centimeter "equivalent") have been measured for a 1.8 Watt hand-held unit operating at 164.45 MHz. The measured exposure diminishes by a factor of 10 at distances of 1 or 2 inches from the site of maximum exposure.

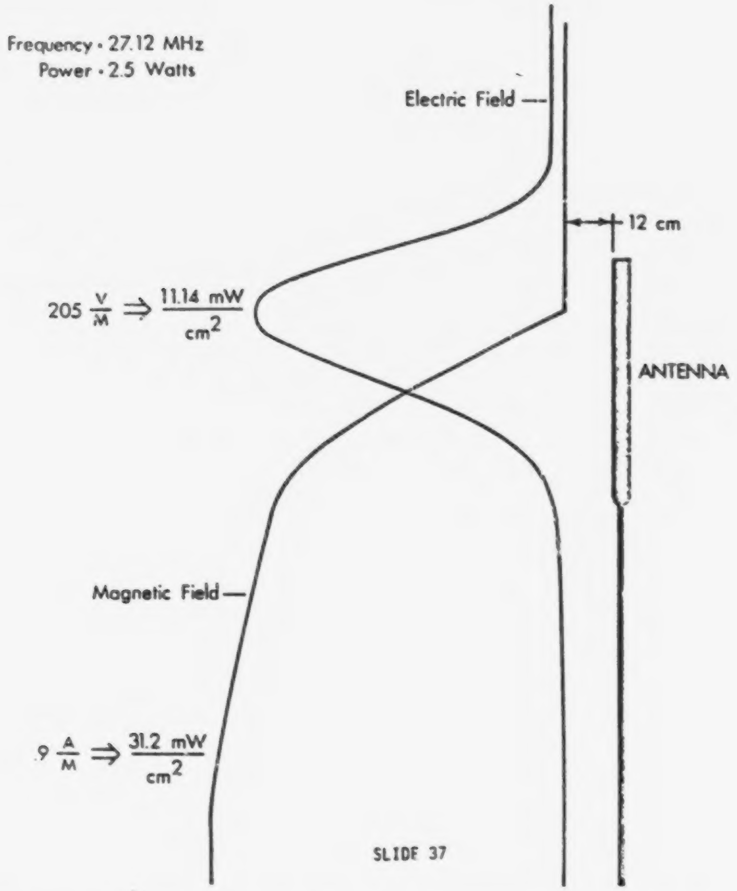

Figure 13. E and H fields from CB radio antenna at 12 cm

OTHER SOURCES

Data is available on the fields produced by other devices such as microwave ovens, radiofrequency heat sealers, electrosurgical units, and medical diathermy units. Since these are not sources of environmental concern, and time is limited, I have excluded them from consideration here.

SUMMARY AND CONCLUSIONS

The low levels in the the general radiofrequency environment are dominated by radio and television transmission. Microwave relay links, low-power radars, mobile communications systems, microwave ovens, and so forth, make almost negligible contributions. Most of the population (99 percent) is exposed to levels less than 1 microwatt per square centimeter. The largest radar field measured in the general environment of one urban area was less than the median value for the broadcast band. These levels are well below the U.S. Occupational Standard and even below the extremely conservative standards of the Soviet Union.

The specific source environment for most broadcast sources is well below 100 microwatts per square centimeter. The only fields in excess of this value occur in the immediate vicinity of some FM antenna towers and on the roofs of tall buildings that are located within a city block or so of FM and TV broadcast antennas. When considering other high-power sources such as radars and satellite communications systems, the potential for exposure of persons to obviously high levels of radiation is small. However, the population exposed to these specific source environments, though small, remains to be determined and is the subject of ongoing EPA studies.

Of the low-power sources, only portable communications equipment produces fields in accessible locations that, at least on cursory examination, appear high. The interpretation of the impact of these fields is difficult and the difficulty is confounded by partial body exposure and intermittent operation. Better knowledge on the rates of energy deposition produced by these devices is needed before their impact can be determined fully. Initial work indicates that tissue temperature increases should be less than 0.1 °C.

Most of the people, most of the time, are exposed to very low levels. Intermittent exposures to higher levels can and do occur. If there is an environmental radiofrequency problem then it is associated with specific source environments, not the general radiofrequency environment as defined here.

DISCUSSION

DR. THIELE: Could you give us an idea of the cost of some of the equipment?

MR. JANES: The state-of-the-art has advanced considerably over what it was when this system was assembled. We estimated it would take a quarter of a million dollars to replace the system we now have. If you want the versatility that is present in that particular system--I think that one can set up to measure generator frequency more or less but not on the order of magnitude though.

MR. ROGERS: You keep making reference to the occupational standard, although I know you do not feel that is the environmental standard. My question is twofold: are you coming up with a general environmental standard on microwave or lower limit, and is there any research being done at the present time to justify such a standard?

MR. JANES: Yes. The whole program is focused on the decision of whether the agency needs to provide some guidance for controlling environmental exposure. We have not reached that decision yet. Though the data show that there are not large population groups at risk, there are three or four things one can say about exposure levels. Power density may not survive in terms of specifying an exposure; things of concern in the near-field and power density is not a very good description thereof. We feel that because the current occupational standard takes into account control of the source, it is probably too high a value to just put out in the environment.

We get into all kinds of games about how you play safety factors. I will give you two points of perspective. The American National Standards Institute group, which is going to put out a revised standard this year, supposedly, over the critical frequency range is considering 1000 microwatts/cm^2, cutting down a factor of 10. The National Institute of Occupational Safety and Health is preparing a criteria document for the occupational exposure for frequencies between 30 and 300 MHz which is probably also going to recognize that we come down to a milliwatt/cm^2 in that frequency range and 5 milliwatt/cm^2 elsewhere. If you talk to some of the people involved directly in biological effects research at our own laboratory, they will tell you that they are beginning to think that anything lower than 1000 microwatts/cm^2 is going to be hard to defend. The way we are looking at things is that exposures that fall between 0.1 milliwatt/cm^2 and a 1 milliwatt/cm^2 are interesting.

FDA'S PROPOSED PROTECTIVE ACTION GUIDES
for
FOOD, MILK, and THYROID-BLOCKING

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Thank you for asking me to talk with you this afternoon about two recent Food and Drug Administration actions. These actions appeared as notices in the FEDERAL REGISTER of December 15, 1978, and will impact directly on emergency planning in case of a nuclear accident. The first involves a proposed recommendation on protective action guidance for the food pathway. The second concerns itself with the use of potassium iodide (KI) as a thyroid blocking agent. I would like to discuss the latter, that is, the KI as a thyroid blocking agent first, since the document is shorter, and my time is limited. That way, I will be able to cover at least one of the recommendations completely.

In its notice in the FEDERAL REGISTER of December 15, 1978, entitled "Potassium Iodide as a Thryroid Blocking Agent in a Radiation Emergency," the FDA did three things:

1. it requested submission of New Drug Applications (NDA's) for potassium iodide in oral form for use as a thyroid blocking agent in a radiation emergency,

2. the agency encouraged interested persons to submit NDA's in the interest of public safety, and

3. the FDA also announced the availability of labeling guidelines for potassium iodide for such use.

Several agents were considered as thyroid blocking agents. Essentially, two types of materials are included - organic materials such as Propylthiourocil and Methimazole, and ionic materials such as thiocyanates, tetrafluoroborate, perrhenate, perchlorate, iodate, and finally, iodide. The potassium iodide was chosen over these other forms because of (1) the degree of blocking achieved; (2) the rapidity of onset of action; (3) the duration of its blocking effect; and (4) the safety compared to the other agents mentioned.

Although potassium iodide acts on the thyroid in several ways, its use for this purpose is primarily predicated on its ability to saturate the iodide transport system. Thus, it effectively abolishes entry of radioiodine. A complete block is achieved, that is, over 90 percent of radioiodine is blocked by the oral administration of 130 milligrams of KI. This is equivalent to 100 milligrams of iodide. The dose for infants under 1 year of age is 65 milligrams. Onset of blocking occurs in 30 minutes. Therefore, administration before or immediately after initial exposure must occur for the best results. However, substantial benefit can also be achieved if the material is given within 3 or 4 hours of exposure. Even up to 12 hours after exposure, some limited benefit will occur.

Most radioiodine not taken up by the thyroid is excreted within 48 hours. However, material accumulated by the thyroid may be leaked back into the general circulation. In order to prevent or curtail accumulation in the thyroid gland from any source, including chronic exposure, a daily blocking dose is needed. The duration of time that a blocking agent is required is not likely to exceed 10 days.

As with any drug, certain cautions have to be recognized. There are no reports of significant toxicity for the use of potassium iodide in asthma or cough preparations. For these uses, it is given in greater doses than for blocking and over a longer period of time. The risk is judged to be low for the short-term use of potassium iodide in a radiation emergency. Although the use of potassium iodide as a blocking agent requires an NDA, the FDA has judged that the safety and efficacy requirements for the NDA may be met by citing published material. A list published within the FEDERAL REGISTER document itself can be used to satisfy the requirements of the NDA. At appropriate dosages and for specific use in a radiation emergency, FDA indicated that the prescription dispensing requirements are waived.

Within the FEDERAL REGISTER document itself, there is no guidance as to when to use potassium iodide as a blocking agent. One must go to different sources for these indications. The NCRP Report No. 55 indicates that potassium iodide should be considered at an anticipated dose of 10 to 30 rads to the thyroid. EPA draft guidelines for action because of thyroid exposure via inhalation indicate that one should consider some sort of action at between 5 and 25 rem.

This ends the portion of my presentation having to do with FDA action concerning potassium iodide as a thyroid blocking agent. I shall now proceed to a discussion of protection action guidance for the food pathway.

This guidance also appears in the FEDERAL REGISTER of December 15, 1978. It is proposed guidance and although the comment period is over, because of its importance, comments will continue to be accepted. These recommendations are for use by appropriate State and local agencies in response planning for radiation emergencies in the event of an accident resulting in the contamination of food or animal feed by radioactive substances. They are to be used as a guide for the conduct of radiation protection activities involving the production, processing, distribution, and use of human food and animal feeds. Events that may result in radiation emergencies include, but are not limited to accidents at nuclear facilities, transportation accidents, and fallout from nuclear devices. Although these incidents could lead to a general contamination of the environment, the FDA's responsibilities specifically relate to food and animal feeds. Thus, the proposed recommendations assume that the population group receiving radiation doses via the food chain will receive only insignificant radiation exposure via other pathways; that is, via external exposure or inhalation. The proposed protective actions are intended for implementation within hours or days from the time an emergency is recognized, and the duration should not exceed a month or two. Other Federal agencies, however, are responsible for recommending countermeasures for exposure to the population for pathways other than for food, and for action of a longer duration, that is, action involving 1 or 2 years.

The FDA protective action guidance does not imply an acceptable radiation dose from food containing radioactivity during normal peacetime conditions. Rather, their purpose is to reduce or avoid further radiation dose to the population via the food chain. Furthermore, these recommendations are not a license to needlessly permit environmental levels of radiation to rise.

Some questions of a legal nature have already arisen during the comment period. These concern the following:

1. Delaney Amendment Issue

   The Commissioner concludes that the establishment of guidelines for radioactive contamination of foods is required to meet our responsibilities as spelled out in the FEDERAL REGISTER of December 24, 1975, by the Federal Preparedness Agency of the General Services Administration. The Commissioner asserts that such action does not stand in conflict with the Delaney Clause of Section 409, or any other portion of the Food, Drug, and Cosmetic Act.

2. "Blending" Issue

A question concerning blending has also arisen. Blending is the purposeful mixing together of contaminated and uncontaminated food. A long-standing agency policy forbids the blending of contaminated and uncontaminated products.

Protective action guides or PAG's are defined as the projected dose commitment to individuals in the general population that warrants protective actions following the release of radioactive material. What does this mean? Specifically, it means:

1. The projected reduction in individual dose is greater than the risk of individual safety inherent in taking the action.

2. The PAG's are based on the projected dose commitment. This term, projected dose commitment, is defined as the dose commitment that would be received in the future by individuals in a population group from a contaminating event if no protective action were taken. The dose commitment is the radiation dose received by an individual to a specific organ or whole body over a lifetime from a single event. In other words, the protective action guidance is based on anticipated or projected doses, and therefore, action is taken prior to the occurrence of those doses. The purpose of the PAG's is to prevent additional radioactive contamination from entering the human food chain and to reduce or avoid future radiation doses to the population after an accidental contaminating event.

Two protective action guidance levels have been recommended. They are:

1. The preventive PAG is applicable to situations where protective actions causing minimal impact are justified. These protective actions prevent or reduce concentrations of radioactivity in food.

2. The emergency PAG is applicable to incidents where protective actions of high impact are justified because of the projected health hazards. Levels at which food should be isolated from commerce are appropriate at the emergency PAG level.

The preventive PAG is (1) 1.5 rem projected dose commitment to the thyroid, or (2) 0.5 rem projected dose commitment to the whole body, bone marrow, or any other organ.

The emergency PAG is (1) 15 rem projected dose commitment to the thyroid, or (2) 5 rem projected dose commitment to the whole body, bone marrow, or any other organ.

The PAG's above have been formulated by the FDA on the basis of a judgment of acceptable risk. One approach for making this judgment is to compare the risk of radiation exposure with the risk of other common hazards accepted by society. For example, the numerical dose commitment limits for the PAG can be derived by comparison to the risks from natural disasters; i.e., earthquake, being struck by lightning, and so forth. This is approximately an annual risk of death of one in a million. This would be equivalent to 200 deaths per year in the United States population. The method of comparison for judging the acceptability of risk that was finally used in the protective action guides employs the geographic variability of natural radiation exposure as a point of comparison. This comparison is advantageous in that:

1. the geographic variability in natural radiation exposure is normally ignored as a risk in a highly mobile society;

2. radiation risks are directly compared with other radiation risks rather than with nonradiation risks; and

3. this comparison yields more conservative numerical limits than comparisons to common societal hazards.

Using this kind of comparison, the risk from the variation natural radiation exposure is about 100 deaths per year in the United States population.

A decision concerning the appropriate characterization for natural radiation exposure must be made. For example, one could employ the average, the population weighted average, the standard deviation, or as in this particular document, two standard errors of the mean natural radiation dose. This latter statistic is an appropriate measure of variations about a series of means. As used here, this statistic for natural radiation is a measure of the variability of average doses of natural radioactivity among the States. It thus provides a means of equating geographic variability for natural radiation. The value for two standard errors of the mean was obtained from estimates of mean natural background doses for each of the 50 States. In the United States, this statistic is equal to 8.5 millirem per year or 6.5 percent of the average natural radiation dose, 130 millirem per year.

Both somatic risks, in terms of cancer deaths, and genetic effects were assessed in the above comparison. Risks from those cancers that arise predominantly from ingestion, namely leukemia, bone, thyroid, and the GI tract, were evaluated. To evaluate the preventive PAG, the whole population was used as the population-at-risk while for the emergency PAG, a population around a reactor site was employed. We use the population within 25 miles of the most populous reactor site, which is about 15 million persons. These populations were employed to establish the PAG limits. However, protective action would be initiated even if the projected PAG limits were anticipated for a single individual in order to protect that individual. A cost-benefit and a cost-effectiveness analysis were also used to check the feasibility of the guides - that is, not as a rationale for setting the guides, merely to confirm its reasonableness.

A practical means of employing the PAG's is through the use of derived response levels. Derived response levels refer to the activity of a specific radioactive substance per unit weight or volume of food, or animal feed, which corresponds to a particular numerical PAG limit previously mentioned. Response levels have been calculated based on recent metabolic and agricultural models. The metabolic model translates activity or microcurie intake to an equivalent organ dose. The agricultural model follows the transfer of radioactivity from initial deposition on pasture to ingestion by man. These models will not be discussed here. Details are given in the supporting document. Suffice it to say that the newborn infant is considered the critical group for calculation of doses for radioiodine-131.

Specific response levels are given in the FDA recommendations for radioactive substances that are thought to be relatively abundant under emergency conditions, easily enter the food chain, and are taken up and retained by the human body. These substances are iodine-131, cesium-137, strontium-90, and strontium-89. Response levels are specifically given for initial deposition on pasture, concentration in forage and in milk, and total intake. As an example, the derived response levels for radioiodine-131 are shown below:

RESPONSE LEVEL

	Preventive PAG	Emergency PAG	
	Infant I-131	Infant I-131	Adult I-131
Initial Deposition ($\mu Ci/m^2$)	0.14	1.4	15
Peak Activity			
Pasture ($\mu Ci/kg$)	0.27	2.7	37
Milk ($\mu Ci/l$)	0.012	0.12	1.7
TOTAL INTAKE (μCi)	0.09	0.9	10

Please note that initial deposition refers to initial deposition on pasture. Derived response levels for pasture and milk are in terms of peak activity. The concentration of radioactivity in pasture is based on fresh weight. For the emergency PAG, response levels are given based both on the infant and on the adult. In the case of an adult, a higher radioactivity concentration is equal to the PAG because of the differences in organ size and body metabolism between an infant and an adult. If food ingested by children can be manipulated so that it is free of radioactivity (i.e., by the use of canned or packaged foods), or if the number of children is small and they can be evaluated, then the higher response level can be used.

One of the questions that has recently arisen about the PAG's is their use under a chronic situation. As I mentioned earlier, we have included in the derived response limits a limit for total intake. This is equivalent to 0.09 microcuries of radioiodine-131. One could use this total intake figure as a basis on which to evaluate a chronic intake. This level, again, is equivalent to a 1.5 rem to an infant thyroid over a lifetime. The total intake could be considered in evaluating average daily intakes over one specific designated time period (i.e., weeks, months, or years).

Variations in the basic model permit calculation of derived response levels for organs other than the thyroid, bone marrow, or the whole body; specific food groups other than milk or meat; and mixtures of radionuclides. Details on how this can be done appears in the proposed recommendations and in the supporting document.

It is interesting to compare this guidance with previous guidance. If one takes the preventive PAG, it is about one-twentieth of the old FRC protective action guidance (PAG's). If one considers the emergency PAG, it is about one-half the old Federal FRC protective action guidance. Another interesting comparison is that at the preventive PAG, one takes action upon anticipating a lifetime dose of 1.5 rem to the thyroid; this dose is permitted annually by the FRC's Radiation Protection Guidance (RPG). The proposed PAG's, at the preventive level, thus indicates that action should be taken should the anticipated projected dose be equivalent to the annual RPG limit.

The PAG's contain information on specific actions to be taken at the preventive and emergency levels for pasture, milk, fruits, vegetables, and grain. At the preventive level, the actions are what one might expect - putting cows on stored feed, and diversion of milk to other marketing processes. Another recommendation is the storage of milk for prolonged times at reduced temperatures. This is feasible, provided ultra-high temperature pasteurization techniques are employed for processing. The supporting document further contains references on laboratory analysis, and more importantly, on field estimation at the emergency PAG level.

My own view of the proposed guidance is that they are just that - proposed. They are not as yet "set in cement," nor do I feel that anything that appears in the FEDERAL REGISTER is "set in cement." Therefore, I would like to conclude this talk with an invitation for all of you to review the PAG's, to review the supporting document, and to indicate to FDA, in writing, any desirable changes and improvements.

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DISCUSSION

MR. SOLON: In terms of potassium iodide's potential deleterious effects, I assume that the 1- to 30-rad figure is one that was based on an opinion or as a feeling that it is contraindicated to employ potassium iodide. From the point of view of its pharmacological potential, why not use it at 1 rad, for example?

DR. SHLEIEN: I do not think there was a specific risk analysis done, but there is very little data in terms of deleterious effects with the use of potassium iodide at high levels over long periods of time. The data that do exist seem to indicate that even when you use it in that way you can expect some side effects in 1 in 1,000,000 or 1 in 10,000,000 doses. These side effects for the most part concern individuals sensitive to iodides, specifically individuals who might be sensitvie to seafood or other foods that contain high iodides. The effects are rashes and allergic type reactions.

MR. SOLON: I would submit that consideration be given to administering it when the dose would be materially lower than the 10 to 30 rads which is unquestionably deleterious in terms of a thyroid dose.

DR. SHLEIEN: Well, first you should write this ospinion to FDA and give your reasons for it, because the recommendation is still in the beginning stages. Second, you really have to be concerned about some of the side effects. You cannot completely dismiss them. They need to be investigated further before making a decision.

MR. GODWIN: Regarding Piedmont Syrup which is a syrup of potassium iodide, could a State, for example, get a stock of that and would your NDA provisions regarding not having a prescription under these circumstances apply? Because this product is already commercially available, it does require a prescription.

DR. SHLEIEN: I am not sure and I do not know if it would be advantageous in terms of using the syrup. I am cognizant of the fact that there are some commercial products that contain KI, but I do not know what FDA's opinion would be on using them as a thyroid blocking agent in an emergency.

MR. GODWIN: Obviously, I think their dose is 300 milligrams per tablespoon. You would have to cut the dose about half.

DR. SHLEIEN: Yes, 300 milligrams, three times a day is usually the dose used in asthma.

THE "TRUTH" ABOUT THREE MILE ISLAND, HARRISBURG, PENNSYLAVNIA and the IMPACT ON RADIATION PROTECTION AGENCIES

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MR. GERUSKY: Yes, Virginia, Pennsylvania did have an emergency plan. There were some people down in Washington that did not know that we had a plan, or did not want to know we had; I was not exactly sure. At times it looked like they felt that we were not competent to have emergency plans and decided to do some things on their own.

It is also very interesting that at the Three Mile Island II hearing, approximately a year and a half before, the subject of emergency evacuation planning was one of the issues raised by the intervenors. Our emergency planning people, State and local spent over a week on the witness stand discussing what they would do if there was an accident at Three Mile Island II; and they got an operating permit. So apparently the NRC hearing board believed that the plan was an acceptable one.

At 7:02 a.m. on the morning of the 28th of March, the reactor operator contacted the State Civil Defense (or Emergency Management Agency; they have changed their name; I am going to use civil defense--it is easier) duty officer. This had been done on a routine planning basis for a long time. In this case he said: "We have an accident; this is not drill. Please contact the Bureau of Radiation Protection and have them get back to us right away."

The duty officer is on 24 hours a day, since the C.D. telephone automatically switches to his home phone number. So if you dial Civil Defense on off-duty hours, you get someone at home. We have a roster of people that we rotate on a monthly basis. In this case it was our nuclear engineer, Bill Dornsife, who was on duty and received the call from the Civil Defense duty officer. He then contacted the plant and found that they were declaring a site emergency, that they had problems with fuel, that they were having all kinds of problems. In Bill's words, it was rather hectic in the control room at that point. His responsibility is to call someone else on the staff, and then head to the office to establish an open line with the facility. He called Margaret Reilly, who is in charge of our environmental surveillance and emergency planning program. She contacted me first and then the other people on the staff.

I was the first one in the office between 7:20 and 7:25 a.m., opened up a direct line to the reactor control room, and at that point, they started to fill us in on the problem. They also declared a general emergency from the site emergency. The site emergency meant that they were evacuationg people from the site because of high radiation levels. They also had high levels in the containment building, when they declared a general emergency.

The dome monitor in the reactor containment read 600 R/hr. Both the utility and our office have duplicate overlays on maps and by knowing the wind speed, direction and weather conditions, one can then calculate (it is already calculated out for us) what the dose rates would be downwind. In this case, it was calculated that the wind was coming from the east toward the west. There is a little town right across the River called Goldsboro. The dose rates in Goldsboro were predicted to be 10 R/hr from noble gases. At the same time, we were on the phone with Civil Defense people who, by that time, had all been called into the office by the duty officer, which is his telephone chain. He has to contact people. We told them to inform York County Civil Defense to be ready to evacuate people from the west side of the River out to at least 5 miles at that point. We requested verification of the numbers, because the parameters include a 0.2 percent per day leak rate from the containment to get this kind of dose rate. So far, the monitors, from what we could gather, had found no increased levels of radiation onsite. A State Police helicopter was at the site by that time (another call that is in our emergency plan--if available, to have a State Police helicopter get to the site). They flew across river and tried to find the plume and also went down on the ground in Goldsboro and took measurements. No increased radiation levels were found at all. We then told Civil Defense to relax and we would get back to them, but to alert the other counties in case something else happened.

The NRC was contacted; apparently they heard about the incident at 7:45. The utility said they contacted them at the same time they contacted us, but in any case they arrived at the site about 10:15 a.m. They started to take readings. They had both their health physics staff and their reactor engineers (their inspectors) who went into the control room.

DR. PARROTT: Tom, was that NRC I & E?

MR. GERUSKY: Yes, the regional office, King of Prussia, the I & E people. The I & E people throughout the period have been at the site, performed extremely well, and I have nothing but praise for the work that they have done, and the information we got from them.

We had an open line with the reactor control room and maintained that throughout the course of the incident. At about 10:45 a.m., we were notified that they were detecting levels offsite in the range of 2 to 5 to 10 mR/hr, and that they could not find anything on their air samplers that would indicate any radioactive iodine being released. There was one sample (they were using a field measuring device, and were using a charcoal cartridge) that apparently read 10^{-8} microcuries per cc iodine. That was the only sample that was reported to be high for iodine. That was in the middle of Middletown, which is directly north of the plant. The situation was such that we wanted to verify that number. They flew the cartridge to us by helicopter, put it on a jelly and found no iodine whatsoever; it was all xenon. It is interesting that xenon likes charcoal, too. That was a problem throughout the course of the event.

We had earlier received a call from Charlie Meinhold at Brookhaven saying "we are ready if you want us." We said, "stay ready; get the helicopter and we will call you." At this point we did not know much about what was going on at the reactor and we were not sure that we needed them. About that time we said we needed them. The DOE emergency response team came in, set up, and did yeoman work for us over the next 3 weeks. People came in from Brookhaven, from Argonne, and from Knolls Atomic Power Laboratory, at least; there were so many coming in and going, but they were the "grunts," as Maggie would call them. They knew how to perform surveys, they knew what reactors were, and they knew what to look for in a reactor accident. They had some specialized air sampling equipment that was available to them, and they were getting no detectable iodines on any air samples. That was something that we just could not figure out; why the devil in a reactor accident, everybody is concerned about iodine, and we were not seeing any.

Well, there was a logical reason for it; the iodine was all going through charcoal filters before it got out of the plant, so it never did get out until later when the charcoal got loaded up with iodine and could not hold any more. They had to replace all the charcoal filters.

The dose rates, as I have said, offsite after about 10:00 a.m., were 2 to 10 mR/hr; all xenon--no iodine. Apparently, after they found out that there was not much iodine, even though they had a sophisticated system, they would go up in the helicopter with just an open

BEST DOCUMENT AVAILABLE

window GM, and do some surveys to trace the plume. But they would be sampling for iodine, and they had a multichannel analyzer available to them to pinpoint whether they were finding iodine or not.

The other thing that DOE brought in was the ERAC system. With the ERAC system, by knowing wind speed, direction, and source term, one can determine where the plume is most likely to go. That is tied in to Lawrence Radiation Laboratory in Livermore. They were constantly updating that and verifying the LRL numbers with their surveys. LRL would come up with a prediction, and they would go out and survey and be right on the prediction. I am recommending that that system be installed in every nuclear power plant in the country.

MR. RYAN: I second it.

MR. GERUSKY: According to the population distributions around the reactor out to 20 miles, if we had to evacuate out to 20 miles, there are a lot of people. I recall a statement that Joe Hendrie made that we should evacuate people out to 20 miles downwind. That whole first week there was no wind, so we would have had to evacuate everybody in an area 20 miles around the plant.

Dairy farms are located in an 8-mile radius around the plant. I could not believe that there were that many of them! They were all sampled. Luckily, most of the cattle were on stored feed, and there was almost no iodine detected on the ground at all. We did find iodine after the first couple of days in milk samples. We think that what happened was when during the beginning of the incident, one of the steam generators went dry and there was a primary to secondary leakage. They isolated that steam generator, but by that time, they probably had released some radioactive material, gaseous fission products to the environment and no one knew it at the time. It did not go out the normal route for sampling. We will get back to that a little bit later when we talk about exposures.

When there is an accident of any kind, people are most worried about their drinking water. We had to sample and show people the drinking water source supplies, north of the plant 20 miles away, that there was no problem with their water. Well, there was not even anything being released of any consequence to the River, yet we had to do it, and we are still doing water samples, and water samples, and water samples.

Now, at this point EPA came into the picture, and I do not know how EPA came into the picture, but they were there. We supplied them with radio cars and their main job at that time was to do a water sampling program. The group that came in was from the Las Vegas Laboratory. I did not even know that Montgomery was available, and we sure could have used them. If I had known, we would have had a lot of Southerners assisting our laboratory in Pennsylvania, because we needed help desperately for milk analysis, in particular. Anyway, we did not find anything in any water supply sources and we still are not.

The LRL system needed more than one meteorological station for plume predictions and so they built some and timed it into a direct telephone wire to LRL and were able to get a lot of interesting data.

Now comes Black Friday. During Thursday, we still were getting conflicting reports from the plant. The Lieutenant Governor went down to the plant, went into the control room, talked to the people, found, he felt, that everyone was calm, cool, and collected; that there was no panic. But I think there was not panic because they did not realize what they had on their hands at that time. In the meantime, the NRC regional people were briefing the Governor and Lieutenant Governor and us at least once a day and sometimes twice a day as to what was going on at the plant and what they were finding offsite. Our people were now equipped, and I want to say right off the bat that we were not equipped properly to handle a reactor accident. We did not have portable air monitoring equipment, or field measuring devices that could have worked. We did not have a communications setup that was readily available to us, that could be used without having to go through a considerable problem to get it. By the next day, we did have radio communications. We had sent people out to do surveys, but we were worried that we would not be able to contact them to tell them not to survey on this side of the River to go to the other side of the River because a wind shift occurred. So we had problems that first day; the second day with radios, it made a lot of things easier. The DOE teams came in with radios also.

MR. RYAN: What were the conflicting reports you had, Tom?

MR. GERUSKY: Well, the most conflicting reports were coming out of headquarters. We were getting word from site and from the NRC people onsite that things were progressing, that things were getting under control. In the meantime, we hear on the wires, that somebody said that a meltdown is imminent. Someone in NRC in Washington had made a statement and it got national wire coverage.

MR. RYAN: This was on Thursday?

MR. GERUSKY: Friday. At that time, because of all these statements being made... Well let's say what happened on Friday, first. On Friday, there was a reading detected of 1200 mR/hr at 600 feet off the ground, 300 feet over the exhaust stack. That one reading apparently caused concern in Bethesda, and a call came in to our Civil Defense people to evacuate downwind, 5 miles (again, with no wind). We attempted to stop that called the Emergency headquarters and asked their reasons for the recommendation. The only reason we got back was that "there is a lot of brass here, and they had decided that I should call." Well, we said, we are overriding you; we are telling Civil Defense not to evacuate. By that time, though, the ball had started rolling, and the word had gone out to all the local Civil Defense people that evacuation was imminent. In our plan, there are two things one can do; you can tell people to take cover for a release that is going to go by pretty quickly, or you can move people. Well, they were not moving people, so they went backwards in the plan (apparently, I really have not talked to them about it too much) and decided that to take cover was the best approach. So they told everyone to take cover.

I went to the Governor's Office. We could not get Civil Defense back on the telephone after talking with Bethesda, so our nuclear engineer ran over to Civil Defense to tell them not to evacuate. And as I headed out for the Governor's Office, I heard on the radio the local Civil Defense director explain to people what they do in case of evacuation. At that time, or slightly thereafter, a call came in from the President to the Governor, saying that he was going to send someone up to the site who could handle the situation. The Governor requested that information out of Washington be stopped and that all information from NRC be released from the site and from the Governor's Office and that Met Ed be persuaded not to talk to the press anymore. In Met Ed's favor they were trying to tell what they believed was the truth, I think, because they were telling us the same story and the Governor's Office. From what I can gather, that is what they believed at the time. It was the way that they did it which causd the problem. They really got some people mad at them. As events got worse, they looked a lot worse also.

Anyway, the evacuation was stopped. Joe Hendrie telephoned the Governor and apologized for the error in the calculations that would have given dose rates offsite of 120 mR/hr, which is what they expected to see, where we were seeing 14 to 20 mR/hr offsite, and it was going down. He recommended that if his wife was pregnant and he had a child under the age of 2, he would like to see them out of the area, because he said "I do not know what is going to happen at that reactor, and I would like to see them out." I looked at the Governor and said, "What do we do now; get them out I guess." It was decided that you cannot separate people; you cannot say that everybody under the age of 2 has got to get out. So we figured, preschooler and then it was decded to close the schools within 5 miles.

The Governor recommended that preschool children and pregnant women in that area leave, and we set up evacuation centers offsite for them. We opened up our State parks. You would be surprised at the number of people who went to the State parks. There is a rule that you cannot bring pets to State parks. That rule was waived. We found out why that rule exists. The State park people are going to have a lot of cleaning up to do.

The plume at 500 feet at noon of that day and evening was right over Harrisburg, where the readings were 0.1 to 0.2 mR/hr. Those were locations where the plume was detected. It did not move from morning to any particular location. It just kind of stayed there and kind of spread out. The wind was 2 to 3 miles per hour, light and variable. We would have had to evacuate, if those levels were really high, we would have had to evacuate out to 10, maybe 20 miles.

Then, on Friday afternoon, Hal Denton came in, and that evening informed us of the hydrogen bubble problem; that there was a hydrogen bubble in the reactor and that there was a possibility that it would explode, depending upon the oxygen generation rate. That is when my famous "Oh, my God!" statement was made, if you were watching CBS Reports a couple of weeks ago. That statement, we learned later, was not correct; there was a error in NRC's calculations, and there was never a possibility of an explosion of hydrogen inside the reactor. They made that statement a couple of weeks ago before the Advisory Committee on Reactor Safeguards, I believe. We knew that was not the case on Saturday evening, but we were really concerned, at that point, about the size of the bubble and whether, if there was a loss of pressure, the core would be uncovered and we would have meltdown. Fortunately, we also had information that if there was a meltdown, there would be time, that there would not be immediate release, that there would be time to get out. At that point, the Civil Defense people started planning evacuations out to 20 miles from the plant in all directions.

We had good emergency plans to 5 miles in two counties. In the York County area, the emergency plan was not a good one, but there is little a State government can do to make local government do anything, including writing emergency plans. They wrote some pretty quickly, and they now have a good plan. I have not seen them. We all got little slips tacked on to our door, saying this is where you go in case there is an evacuation. We had to head down almost to Maryland. They were really spreading people out.

Then came the press. The local press were great. They were trying to give out the facts. The national press was a problem. They had to find stories, and if anybody saw Middletown deserted on one of the national TV networks, the reason that it was deserted was because the TV newsmen asked everybody to go inside and get off the streets so they could show the streets deserted. They did not have anybody else to talk to but themselves, so they were interviewing each other concerning what they thought could happen at the plant, since nobody was available to talk to them. My wife saw on New York Channel 11 news (we have a cable and watch the Yankee games at home; she watches the news), and according to that Channel, the whole Harrisburg area had been evacuated and may never return. On Saturday Night Live, they were having a vote to decide the next name for the new capitol of Pennsylvania.

As a sidelight, during this evacuation of pregnant women, there was a telephone call. The Governor has a hotline number which people can call in and complain about a lot of things. That one was used for information, and we were trying to provide the people over there with some information so that they could answer the public inquiries. You forget about doing it for 5 hours or 6 hours, and all at once everything has changed and they are telling them stories that are 5 or 6 hours old. In one case, after the evacuation of the pregnant women and small children, one guy called up and said how far away do I have to be from the plant to have sexual relations. And they did not know how to answer that question. So he decided to call a local radio disc jockey, who, you know, knows everything. He called up, and asked the question, and the guy said it does not make any difference, you know, go ahead enjoy yourself. Five minutes later, a call comes in from an obstetrician and gynecologist saying that was wrong; he could get that girl pregnant, and in the early stages of pregnancy are when the worst possible radiation exposure could occur. Oh, man! This is so typical of what went on; it was weird.

Most of the people in the Governor's Office had seen The China Syndrome and were planning who was going to play their roles. One legislator, who did not live too far away, said if we saw the lights in the Governor's Office go out, that was when he was taking off, and my neighbors were all watching Pat to see if she was packing the car, and if she did not pack the car, they were staying.

After Friday, we were inundated with people. I do not know how FDA got there either, exactly, but they did some good. They did a lot of milk sampling, and unfortunately it went to Winchester. The Winchester lab performed very well, and did provide us with a lot of data. During that same time, the Federal Department of Agriculture shut down meat packing plants in the area. They thought that the meat would get contaminated and we had to convince them that the meat was alright. EPA, FDA, DOE, and NRC's whole staff started to come in. I drove down to the site, I think it was Saturday morning, and there was a real problem of communications with the reactor and offsite agencies. There just were not enough telephone lines. I never saw so many Bell Telephone trucks and guys carrying big cables around. They were setting up a massive communication system and they did it very well. On Friday, also, direct lines were set up in the Governor's Office to the President and to Denton's office down there. Direct lines were set up between our Office and I & E trailer. We had direct lines with NRC, Washington; we had direct lines with FDA and we had direct lines to DOE. DOE was being set up at the capitol city airport, which is across the River, and was available for their helicopter.

The system started working very well after Friday. We had communications established that we knew from that point on what was going on. If you read the newspaper article where I had said that after 3 hours, we could sit back and watch, it was after 3 days. After 3 days, we could pull our people out, because we were just running into the Feds with our cars. So we just decided we would listen in on the radio, listen to what they were doing, and have the open lines, and get the data, and use it to make decisions. Our people had to staff the office 24 hours a day, and we did not have that many people who are--I was going to say, who are used to handling reactor accidents. We do now. We did not have that many people who are acquainted with our emergency plan.

Our Legislature was the same way. They had legislation 2-1/2 years ago to give us increased support for environmental monitoring and emergency planning, but when Washington comes out with documents that say that the probability of an accident in a nuclear power plant is like getting hit by a meteorite, it causes problems in trying to get $300,000, or $400,000, or $0.5 million in more money for your program to handle an accident that is never going to happen. That, I think we all have no more problem with. Accidents can and will happen, and they probably will in the future. Let's hope not there.

Stations were set up around the plant later,continuous monitoring stations, by EPA. The highlight of the whole time, right in the middle of all kinds of problems, the President and his wife show up.

Now we get to an evaluation of exposures. If you notice, the State of Pennsylvania has all of four TLD stations around that plant. That is inexcusable. Med Ed had 20; they were mostly close in to the plant, and they were all read on the 28th, late in the day. Then late in the day, NRC put out, on the 28th, TLD's. So there was a period of time when only the Med Ed and our TLD's (our TLD's were right next to the Med Ed TLD's just checking on them, and that did not do any good for evaluation of exposure); so there were only 20 TLD's, and most of them were in close to the plant. DOE came up with some estimates on exposures that occurred from xenon over the first week. As you can see, that 10-mile line, the exposures were beyond 1 mR in some of those areas. This is total for the first week, based upon TLD readings.

The TLD's around the plant, I do not know if you can read the numbers, there is a 30, 40 line, 50, 60, 70, 80, and out to 10 miles it was down to 1 mR.

There were a couple of TLD's on an island just north of the main island, a little island. There was one TLD onsite that read about 1,000 mR, and that was picked up early in the calculations. There was another TLD on that little tiny island directly in front of the main Three Mile Island that read in the range of 400 mR. On the island up higher called Hill Island, there were some people on that Island during the first couple of days, and there is some concern, that I have anyway, as to maybe we did not know that radioactive material was being released earlier than the 10 a.m. time, because that 400 to 600 number (and there was a 900 number, too, side by side on that little island), it looked like there may have been a drift of gases up river. We are not sure, and I do not know if we will ever know. The previous curve has changed, based upon that later dosimeter reading. The earlier readings that we got from that site were low, and we have got to figure out why there is a disparity between the two numbers.

There were 850 samples taken as of 4/11/79; air, soil, water, vegetation in that area--99 percent of them were negative.

Ernie Sternglass came by on the second day of the event and in a local newsapaper, he called me an "evil man," and that I should be fired. The next day, I came in to work, and over my door is a sign: "evil man." I did go to Church and get exorcised, so I am not evil anymore.

Before I finish, in a meeting earlier this week, I read to you some comments or lessons that were penned by Margaret Reilly. They are too good not to repeat. I will repeat some of them, and I cannot repeat all of them, but I think they are important and I think you ought to remember them. These are not in any order. She has not even started and she has 4 pages.

"Don't plan beyond the time frame of the first 4 to 6 hours. After that the event has assumed its own identity and has a life of its own.

"Interactions of individuals and agencies are very much a function of mutual respect and confidence prevailing at the time and as such transcends planning.

"The judgments of responsible individuals depend upon training and experience, not on glossy four-color plans.

"Emergencies cannot be managed from Bethesda, only screwed up.

"Emergency management cannot be effected by a group in Bethesda who otherwise cannot agree on anything.

"Isolate your decision makers from the press and from the miscellaneous phone calls during the peak crisis.

"Have several confidential phone lines in place and change the number after each crisis.

"Don't be afraid to put nonessential calls on hold, or to hang up on the nitwit.

"Don't throw everything you have in at the beginning; people do fatigue. These events last a long time.

"Carry a tape recorder and talk to it regularly." (That was a problem during the first 3 days in trying to recreate it; we just did not have time to take notes. We were moving so fast. We should have had the tape recorders.)

"Get about twice as much communications equipment as you think you will need and use it regularly.

"Everybody is an expert in reactor emergency management and they are not afraid to step forward.

"Keep on hand a supply of antacids and analgesics. (We have a jar of Rolaids labeled 'TMI mints.')

"When attempting to make field estimates of airborne iodines, use silver zeolite; noble gases love charcoal. Noble gases will screw up your background, also. Noble gases are gases and will obey gas laws. They diffuse nicely. Staying indoors when nobles are at fault, doesn't buy crap if the plume is near the ground.

"The chemical form of radioiodines is of enormous importance. Organics don't settle out well, and they don't rain out well. I love organic iodine.

"Events do not fulminate as many had believed. They develop at a rate sufficient to catch the attention of those who will ignore your plan and muddy the water.

"Many people in high radiation positions are operating with obsolete knowledge.

"Radon measurement is a growth industry.

"Radon is as ubiquitous as nematodes; seek and ye shall find." (And that is a result the survey performed on 700 people, whole body counter, and we found 9 people with high radon daughter concentrations in them. If we start looking we are going to find it.

There were a lot of lessons that we learned. One of them that was not mentioned is that for some reason, people at very high levels may have very little knowledge and seem to want to get involved with their experience and to try to help us.

I think that once we got over the problem of having press statements out of Washington and decisions being made there, and then having them made from the site by top level people, we were well on our way to properly handling the accident. We needed all the help that came from the Federal agencies even though there is still a battle going as to who is going to get credit for all the work that has been done, I do not care who gets credit as long as it gets done. It is getting done and is getting done well.

MR. RYAN: I think there is something misleading about the title of the meeting today; the truth about TMI, and if there is any expectation that we will be disclosing the inside poop about the sequence of events that led to the accident, dispel it immediately. We will not know that for a long time.

I had not expected, quite frankly, this kind of format, and I do not have a prepared text, but I would like to talk to some of the issues that bother me; some of the points that Tom raised and then make some general observations.

When I came to the NRC about 3 years ago this month, I spoke to Doc Collins, who is in charge of emergency preparedness as far as State and local governments are concerned in our organization. I said to him: "Doc, what is the story here? Where do we stand on emergency preparedness for State and local governments?" And he said something then which was true then and I suppose it is true now. He said that the NRC is going to have to pay more attention to emergency preparedness for State and local governments in the future than it paid in the past. And I said: "Doc, what will it take to get the Agency to do that?" And he said: "Probably an accident at a nuclear reactor." I think that it is true that in the future NRC is going to pay more attention to emergency preparedness with State and local governments than it did in the past.

There are a number of problems in that area which bother me, some of which Tom has mentioned. One is this question of financing. Tom and his PEMA, the Pennsylvania Emergency Management Agency, went to the Legislature a couple of years ago and were turned down on funding for preparedness purposes. I think that is true in a number of jurisdictions at the State level. I think it is also true at the local level. Very many counties in our country are strapped for funds to run the school buses, let alone to engage in this kind of preparedness planning.

I am also worried about the number of local governments. I think that if there is a deficiency that I would like to put my finger on in this whole area it is the preparedness level of local agencies. The States wherein reactors are located in one form or another are all engaged in some form of emergency preparedness planning. The counties I cannot make that statement for. We project right now there are about 150 counties out there around existing nuclear facilities, and I cannot give you any assurance about the level of preparedness, or the existence of comunications equipment, or the sophistication of the instrumentation. As a matter of fact, in many instances, I suspect the instrumentation is entirely lacking.

To address these two which I regard as pivotal problems in the area, about a year ago, Doc Collins put one of our colleagues to work, Dr. Steve Solomon, on a study of this matter. I am sure Steve has visited with some of the people in this audience in the course of the last year. He went all over the country and visited with county officials, State officials, and reactor operators, and environmental groups, and public interest groups, and so on. And curiously enough, he produced a report on the 27th of March 1979, the day before Three Mile Island. He tried to intimate in that report the costs of carrying out emergency preparedness by States and by localities, particularly counties (in some cases municipalities, but mostly counties) through the turn of the century. He projected that, using the then current estimates, which, I suppose are subject to change, there would be over 120 nuclear units in operation. If we use the projection of the NRC-EPA task force, which recommends an emergency planning zone out to 10 miles from a reactor site, he projected there would be upwards of 350 counties needing this. He also did a current survey on the counties, and I think the number was 140-some.

He tried to estimate what the costs would be from the point of view of training, instrumentation, communications, developing the plan, exercising it periodically, and he came up with a gross figure of $147 million, which sounds astronomical at first, but if you break it down and you realize that we are talking for the next 21 or 22 years, that is a manageable sum. His recommendation was that the NRC look to the utilities as the source of the funding for this effort. The rationale was as follows: there would be no need for Westchester County in New York to engage in emergency preparedness for a fixed nuclear facility if the fixed nuclear facility did not exist. If it were elsewhere, some other county would have that gig. He looked for a political science principle to justify it and he found it in the recommendations of the Advisory Committee on Intergovernmental Relations, which suggested that as a matter of public policy, when there is an expense imposed upon a government by virtue of a particular installation or a particular activity, the best course of action would be for that government to go to user charges, or to cost recovery. He estimated that the entire funding for this emergency preparedness operation might be carried out by doubling the current licensing fee for a nuclear reactor and creating a treasury fund which could be parceled out to State and local governments as the need arose, pursuant to regulation, or on the basis of the needs of the county, all the time, of course, drawing interest, so that the funds would be revived by interest payments.

That report is in draft form now. It has been circulated to a number of people, I am sure to some people in this audience, to a number of States, local governments, to all of the people with whom he visited over the course of the last year, and to environmental groups, public interest groups, utilities, and so on. I expect that that will form the basis of some kind of a recommendation from our office to our Commission, and ultimately, I suppose, to the Congress, about how the problem ought to be handled in future times.

Let me turn from what are two central problems which bother me, and talk about the incident itself, if I may, for a while.

I think Tom and his people and Colonel Oren Henderson and his people in Pennsylvania performed extraordinarily well under extraordinarily difficult circumstances. I think that should be the heading for the comments. I think we will underscore that. It was extraordinarily difficult. I appreciate Maggie's comments about Bethesda, but let me give you what I understand the transaction to be, and how the thing went down.

We had activated what is called an "emergency center" at NRC on the first day of the incident; it was a Wednesday, the 28th. I was curious about Tom's mention about conflicting things coming from the reactor site on Thursday, because Thursday, it seemed to me to be a sort of quiet and very pacific kind of day. Nothing much happened in Washington; the emergency center was in operation. It smelled like a Big Mac, but it was a rather calm day. As far as everyone could tell, the incident was in hand and it was rolling down. But Friday morning when I arrived in my office, I had a call from Doc Collins about 9:30 or 9:45 a.m., asking me to come over. When I got there (this place, by the way, is 1/2 mile away from where I work), he had been on the phone with Colonel Oren Henderson, and he had conveyed to Colonel Henderson the judgment of the people sitting around the table (this was about 10 a.m., I guess) that the situation was deteriorating, that the analysis, the 1200 mR release had been noted, there were burps expected in the immediate future. The calculations were unusual, to put it mildly; the accident was not of the sort which had been previously analyzed. Of course, we did not know at that time that the core had been exposed. But the recommendation of the principals sitting around the table, including Harold Denton, by the way, was that as a precaution, we ought to recommend to Colonel Henderson that he consider an evacuation--an evacuation out to 5 miles. There was a great, I think sober, consideration of this matter by these people sitting around the table, and Doc dutifully conveyed that message to Colonel Henderson.

I was interested to hear Tom talk about a conversation between Joe Hendrie and the Governor. It is interesting to compare the two sides of the conversation. I had never heard this side of it. We recommended that the Chairman speak to the Governor; what we heard first from one of the Chairman's assistants was that the Governor and the Chairman had talked, and the Chairman had recommended a general evacuation of out to 5 miles. Obviously, the Commissioner's assistant was ill-informed. Then the Chairman himself called, and told us that he had recommended to the Governor a precautional evacuation of out to 5 miles for pregnant women and preschool age children. This interplay of 1, 2, 3, 4, and 5, and "if I had my wife there" did not come through from our conversation with our Chairman.

I think that it is interesting that things seem to get better as far as communications were concerned later on Saturday. I am glad to say that some of our people were with Tom in his office; some people from our own office, whose names you may recognize. Wayne Kerr went from Albany, New York; he was up at Sherwood Davies' office. I called him on Friday noon and asked him to get down to Harrisburg. We had also been told that the airport was closed, so I told him to drive. Closed to all but emergency people and press, we were told. Other folks from our office drove; Joel Lubenau, John McGrath, later John Vaden, John Kendig, went up without pausing to get lunch, or a bag, or anything else. Jumped in the car and drove up there, beginning about noon on Friday. We had Joel and John Vaden spelling one another in Tom's office for, it seemed like an eternity, I guess it was only about 10 or 12 days. As Tom pointed out, we had an open line thereafter.

I would point out though that things were bad from the point of view of communications between the Federal Government and the various agencies arriving on the scene, but it is also true that the situation at the reactor seemed to have gotten better as we got into Monday and Tuesday of the following week.

I might say that the first time I heard about the hydrogen bubble was about 10:30 or 10:45 a.m. on Friday morning, and Roger Mattson came in. By the way, the New York

Times reported that there was a conversation between Roger Mattson on site and Joe Hendrie, I guess about 1 p.m. on Friday, in which Dr. Roger Mattson from NRC, said: "I have got to tell you, Joe, you have got to get those people out of there." That was an accurate description of the conversation, but the conversation occurred with Roger Mattson sitting next to me in Bethesda, not from onsite. He did not go up with the first wave. He stayed behind. The helicopter took Harold Denton, Vic Stello, and a crew of principals from Harold's office up.

One of the points that Tom mentioned, and I burst out in the course of his talk, was ERAC. I said that I second his motion. ERAC is a sophisticated atmospheric release calculation model that would allow almost instantateous analysis of various data, and would project a course for an operator reactor in the midst of an emergency. I think one of Denton's allusions in the course of things is valid here: he said it is like a plane where there is something wrong, and the pilot might be pleased to inform everybody in the world about what the difficulties are with the starboard engine and that kind of business, but his first concern is to bring the plane safely down and bring the people down who are in the plane safely, also. It is in my judgment silly to have a sophisticated technology like a nuclear reactor relying on hand calculations in time of crisis for atmospheric releases and for wind shifts and that kind of business. And it is more ridiculous when you think the capability for doing something more sophisticated is at hand; the ERAC system of the Lawrence Livermore Laboratory, which, as Tom pointed, was brought into play at Three Mile Island. I think that it is analogous to hauling a space craft to a launching pad with an oxcart; it just does not make sense to wonder whether your grease pencil is sharp or not in a time of crisis like that when there is at hand a means of doing something more efficiently and more creditably. What we need in that program and what I have urged on our Commission is more money for it.

I agree most sincerely with Tom when he says that he thinks it should be in every reactor in the country, and I second that. It is overdue; we do not have a great deal of money in our office, but we did put up some $50,000 (it sounds very miniscule, I suppose, compared to the Federal budget, but if you compare it to our own budget, it is a lot, a sizeable piece of change). We did not put that up to keep the ERAC notion alive and to test the feasibility of using it in a particular State, in this case, in California. I think that that is the wave of the future. There are a number of publications on it, and I would be happy to send any to anybody who is interested in it.

One thing I do want to stress, maybe a lesson learned, perhaps not as poetically put as Margaret, not in the form of an aphorism, but we ought to, it seems to me, be looking to the question of who does emergency preparedness planning at the State level. A number of years ago, we wrote to the governors, and said, who in your State is responsible for radiological emergency preparededness planning? We got back 50 letters and roughly 25 of them said our State Civil Defense emergency preparedness office and the other 25 said our radiation control office.

DR. PARROTT: You got 51 letters; you got two from Oregon, but from different offices.

MR. RYAN: That figures. Oregon has always been very strange in my estimation. Actually we got more than that. We got two letters from two States; Michigan and Maine that said that the State Police are in charge of the planning effort.

We should also look, and look carefully, it seems to me--particularly in radiation offices in States where there are nuclear reactors, but where the office may be small--about the ability and capability and in many cases the sheer numbers of people who can engage in this kind of planning. We ought to look at it particularly in light of events, like the creation of FEMA, the Federal Emergency Management Agency, which may have some wherewithal when it gets off the ground for assisting States in this kind of planning.

I would not be able to go back and look Doc in the eye if I did not say something about the idea of concurrence; the NRC concurrence in a State radiological emergency plan. This was a responsibility Bernie mentioned; the FEDERAL REGISTER Notice of the day before Christmas in 1975, which assigned responsibility to FDA and also assigned responsibilities to NRC. One of those reponsibilities was to review and concur in State radiological emergency response plans. I emphasize this concurrence notion is not predicated on any statute, and I also emphasize, as I am sure you know, that it is not accompanied by any grant. It is rather on the basis of persuasion and urging and suggesting. We do have some training programs, as you know, but basically there is no money passing from our office to the States in connection with this planning effort or in connection with this concurrence effort. The idea of a concurrence I think is a good idea. You can quibble with the elements that may be contained in the plan, and you can say that this element is desirable and that one is incidental and this one is essential and that kind of business, but the idea that there should be some kind of a standard by which to judge the adequacy of the State plan I think is a good one. One of the essential elements that we always talk about is communcations, and I think that it is a stumbling block for the concurrence in a number of State plans. To tip my hat to Tom, we did know that Pennsylvania had an emergency plan for radiological accidents. We know that a lot of other States have them. Right now, we have had 12 States which have achieved this NRC concurrence. There are a number of States in which there are active reactors which have not. We are urging them orally, and I hope our Chairman will ultimately be sending letters to the Governors saying "please, let's get on with this emergency preparedness. It is more important now than it was a month ago. We think that there is much to be done and if we can assist you, we would be happy to."

That is about all. I think I go back and punch up a couple of highlights. It has been difficult. It has been difficult for people in the NRC, it has been difficult for the people in the State of Pennsylvania. I think the people in the State of Pennsylvania have behaved and conducted themselves exceedingly well under exceedingly difficult circumstances. I think the people in NRC have done the same.

DR. SHLEIEN: The role of the Department of Health, Education, and Welfare (HEW) in control of radioactive contamination of food and in other emergency actions during the Three Mile Island nuclear accident was delineated in an interagency agreement issued by the Federal Preparedness Agency (now part of the Federal Emergency Management Agency) in December 1975. This agreement charged the Department of Health, Education, and Welfare with:

a. issuance of guidance necessary for evaluating and preventing the radioactive contamination of food and animal feeds,

b. formulation of recommendations on, and facilitating the use of, prophylactic drugs to reduce radiation dose to specific organs. This refers, in particular, to the use of potassium iodide following a contamination accident, and

c. provision of guidance on emergency radiation doses related to health and safety of health personnel and assistance to State health departments and other professional organizations in developing plans for the prevention of adverse effects from exposure to radiation.

Formal responsibility for emergency nuclear incident planing was delegated by the Department of Helath, Education, and Welfare to the Food and Drug Administration (memorandum of November 16, 1976) and within FDA, specifically, to the Bureau of Radiological Health. Certain aspects of these responsibilities are part of the ongoing activities of the Department and FDA. For example, the Department planning and organizing of systems for emergency medical services, or the FDA's traditional role in insuring the safety of food, required only redirection or expansion of existing activities to function under emergency conditions. Other roles, such as facilitating the availability of a thyroid-blocking agent and providing advice and guidance to emergency medical personnel on radiation problems were exercised for the first time during the Three Mile Island nuclear accident.

In addition to the above responsibilities, the Department, through the Communicable Disease Center (CDC) and the National Institutes of Health (NIH), is charged with gathering health effects information. A program for assembling known information on exposure levels, and for determining the feasibility of a long-term epidemiological study, was investigated.

The FDA cooperated with CDC and NIH, and the State of Pennsylvania in placing thermoluminescent dosimeters in the environs of the accident site for the measurement of external exposure levels. Further, FDA advised CDC and NIH on methods for determination of any internal human exposure which may have occurred.

Cooperation between HEW, the Environmental Protection Agency (EPA), and the Nuclear Regulatory Commission (NRC) was closely coordinated immediately after the accident at an Incident Center established by the NRC near Washington, D.C. This permitted a free exchange of information. Interagency cooperation was exemplified by a joint effort to assess the population dose and health effects to residents within 50 miles of the Three Mile Island Nuclear Station. Later, the environmental information gathered by the above agencies, the Department of Energy (DOE), and the State of Pennsylvania was linked by a single computer system and all environmental sampling and data-gathering coordinated by the Environmental Protection Agency.

Throughout the crisis, direct assistance in terms of trained manpower at the site was provided to the State of Pennsylvania, and both the Department and FDA were prepared to provide the Governor with further assistance should the need have developed. A Department team included health physicists, physicians, epidemiologists, and field investigators. States contiguous to Pennsylvania (Maryland, New York, New Jersey, and Delaware) were included in the planning process and sent representatives to a joint meeting to discuss the application of proposed FDA protective action guidance. On the average, about 25 FDA staff members were available for sample collection and assistance to the State. Between April 2 and 4, 39 FDA staff members from the Office of the Executive Director for Regional Operations (EDRO) were engaged in sample collection.

The Food and Drug Administration performed the traditional role of insuring the safety of the food supply, and because of expertise in the radiation area, FDA aided the Department in precautionary activities related to potential health problems from radiation exposure. As part of its normal duties, the Food and Drug Administration monitors radioactivity through the collection and analysis of twelve composite samples representing the total diet collected in ten United States cities. A similar program examines selected imported foods for radioactivity. Special projects analyze foods near eight nuclear power plants for tritium and for radium-226 in food grown in phosphate mine trailing areas of Florida.

The sampling program described above was rapidly expanded by the Executive Director for Regional Operations (FDA) during the Three Mile Island accident. The Three Mile Island accident occurred on the morning of March 28, 1979. By March 31, FDA had collected 77 samples including fish, water, and milk samples. The sampling and analysis plan in effect at the end of April called for FDA to:

1. Continue to collect and analyze samples of raw milk for radioactivity at the six sites that have been sampled since the accident, and increase sampling of raw milk to an additional eleven sites that had previously been sampled by the State of Pennsylvania, Department of Agriculture, if required. The milk sampling activity also covers goat, as well as cow milk.

2. Continue to sample and make radiation level checks of other foods (including processed) at 32 selected key indicator firms located within a 20-mile radius of the nuclear reactor plant.

3. Sample tap water during food sampling visits to some of the food processing firms within the sampling territory. Fish samples have also been collected and analyzed.

By April 30, FDA had collected 1,373 samples and analyzed 1,263 for iodine-131, cesium-137, and other gamma-emitting radionuclides. Analysis for strontium-90 had been initiated. However, because of strontium-90's production and release characteristics, it should be present, if at all, at levels lower than the above radionuclides.

Of the above samples, 49 showed positive results for iodine-131. Iodine-131 levels were estimated to be between 13 and 36 picocuries per liter in cow's milk (±10 picocuries per liter). Iodine-131 levels in the range of 300-400 picocuries per liter of milk have been reported in Pennsylvania in milk previously because of fallout from Chinese atomic tests. The dose to the thyroid of an infant drinking one liter of milk daily during the time in which positive milk samples were detected, due to the Three Mile Island accident, would be 5 millirem over the lifetime of the individual.

Estimates of the probability of developing radiation-induced thyroid cancer is about one in ten thousand for 1,000 millirem dose to the thyroid gland. Hence, the thyroid dose of 5 millirem from the Three Mile Island accident, assuming no further releases of radioiodine, is associated with a probability of developing thyroid cancer of one in two million. This risk estimate is based on cancer incidence related to external x-ray exposure. The risk of developing thyroid cancer from radioiodine-131 is estimated to be one-third to one-tenth the risk due to external irradiation because its radiation dose is delivered over an extended period of time.

Cesium-137 was also detected in 35 milk samples. Levels were between 11 picocuries per liter and 37 picocuries per liter (±10 picocuries per liter). Cesium-137 can be expected to be present in milk, especially in the spring, when residual radioactivity from weapons-testing enters the lower atmosphere from the stratosphere. Cesium-137 in the milk around Three Mile Island is attributed to this source because of its detection in milk samples at points distant from the accident.

On December 15, 1978, the Department had published proposed recommendations for Accidental Radioactive Contamination of Human Foods and Animal Feeds (Protective Action Guides) in a Radiation Emergency. The proposed Protective Action Guides provide guidelines and recommendations for action to be taken in the event of a radiological incident resulting in the contamination of human food or animal feeds. These guidelines and recommendations are for use by State and local agencies responsible for formulating response plans in the event of a radiological incident and were applicable to uncontrolled releases of radioactivity which could have occurred at Three Mile Island. The proposal establishes a set of guidelines that can be used to determine whether levels of radiation encountered in food after a radiological incident warrant protective action and would suggest appropriate actions that may be taken if action is warranted. A supporting document explains the use of the guides.

The point at which action to prevent further introduction of radioiodine into milk is an anticipated total intake of iodine-131 calculated to be 90,000 picocuries, which could give a lifetime dose of one and one-half rem to an infant's thyroid. This level need not be reached, merely anticipated prior to taking action. It is equivalent to a peak concentration of 12,000 picocuries of iodine-131 per liter of milk from a single incident of brief duration. The iodine-131 levels reported above are 300 times smaller than the preventive action level.

Another traditional HEW rule is responding to State requests for assistance on health problems. The Food and Drug Administration, while not directly involved in this function except in questions of food safety, assisted in the training of 30 medical and allied personnel at the Baltimore Public Health Service (PHS) Hospital in the medical aspects of radiation accidents. A field guidance documentary on the determination of contamination by emergency medical technicians, decontamination of emergency medical vehicles and field determination of radioactivity in food was made available to the trainees and the State of Pennsylvania (over 300 were distributed).

During the Three Mile Island accident, the FDA arranged for the manufacture and stockpiling in Harrisburg, Pennsylvania, of potassium iodide solution for use as a thyroid-blocking agent (to prevent the uptake of radioiodine). The process of making potassium iodide available for this purpose began on December 15, 1978, with the publication of a request for submission of New Drug Applications (NDA) for Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency. The agency encouraged interested persons to submit NDA's in the interest of public safety. The agency also announced the availability of guideline labeling for potassium iodide for such use.

There was no readily available supply of the drug for the population (about 1 million persons) within a 30-mile radius of the accident site at the time the accident occurred. However, FDA's Bureau of Drugs successfully obtained 250,000 ounces of potassium iodide solution, USP, packaged in one-ounce dropper bottles. Each bottle had a sufficient quantity of iodide solution to accommodate the needs of an entire household of four throughout the incident. For greatest effectiveness, the drug should be administered before the radioactive iodine is inhaled or ingested. To maximize its effectiveness as a thyroid-blocking agent and to inform persons of the potential side effects and risks associated with its use, Bureau of Drugs personnel had 250,000 patient information sheets printed and shipped to Harrisburg so that each bottle could be supplied with a Patient Information Sheet.

The logistics of distribution of this material was carefully orchestrated with the plans of the Federal Disaster Assistance Agency and its local units. Conditions under which use of the drug should be considered are available in a recent publication of the National Council for Radiation Protection and Measurements (NCRP Report No. 55); these conditions were not encountered during the accident.

Because uncertainties still remain about the relationship between low-level radiation and cancer, the Secretary of HEW was directed by the Congress in Public Law 95-633 to "establish a comprehensive program of research into the biological effects of low-level ionizing radiation." As part of this health effects program, the Communicable Disease Center is investigating the feasibility of a long-term epidemiological study encompassing the population around Three Mile Island. The FDA, as part of this study, has had in place on any single day as many as 237 thermoluminescent dosimeter packages (eight TLD's per package) at 173 sites to measure external radiation. The initial placement of TLD dosimeters was carried out on the evening of March 31, and by the evening of April 2, all were in place--supplementing measurement devices maintained by the utility, the State, NRC, and EPA. The dosimeters were distributed over a 20-mile radius around the reactor site with the bulk of the dosimeters placed within a 10-mile radius. The dosimeters are collected and replaced periodically to establish the time relative dose pattern. CDC is also working with the Nuclear Regulatory Commisson to develop a registry of workers at the Three Mile Island facility as part of the potential epidemiological study.

Bioassays for internally emitting radionuclides include collection of urine samples and exposure histories from 33 residents living in close proximity to the plant. The samples were sent to NIH for radiochemical analysis and preliminary results indicate no detectable activity. An examination of 721 persons who lived close to the site by whole body counting indicated them to have no internal contaminations attributable to the accident. This screening program was conducted by the State of Pennsylvania and the NRC. Although FDA is not directly involved, these data are complementary to the TLD results being collected by FDA.

What of the future? There are several radiological control problems associated with clean-up. The radioactivity remaining in the reactor containment is primarily cesium-137 and iodine-131. Cesium-137 has a half-life of 30 years and is a gamma emitter. Iodine-131, with a half-life of eight days, will remain as a potential public health problem for the next two or three months. Iodine-131 can readily become airborne and potentially expose humans via its transfer through pasture, cow, and milk to man. Cesium-137 presents a potential long-term problems. However, because it is less likely to become airborn than iodine-131, exposure of humans by the above exposure route is doubtful. Exposure via drinking water and/or fish could still be a problem if cesium-137 is inadvertently released into river water. EPA is sampling drinking as well as river water.

FDA will, at an appropriate time, modify its sampling program, shifting emphasis from sampling raw milk to sampling market milk. Sampling of locally grown fresh produce may be initiated since it may be a significant indicator of total intake for non-urban populations. Sampling of market milk at processing plants will continue to provide coverage of all milk produced within seven miles of the plant.

During the Three Mile Island nuclear accident, FDA fulfilled its traditional role of insuring a safe food supply, and together with HEW, it provided advice and assistance in the solution of health problems. This included protective action guidance relative to food and assuring the availability of sufficient quantitites of a thyroid-blocking agent, potassium iodide. Together with the NRC and EPA, and other HEW agencies (CDC and NIH), FDA aided in estimating population doses around the accident site which would be essential for future epidemiological studies should they be decided upon as useful. In cooperation with other Federal agenies, there was, and continues to be, a free exchange of information as well as joint efforts to determine the magnitude of radioactivity in the environment, and to estimate population doses and potential health effects from the accident. The FDA provided, at the State of Pennsylvania's request, trained health physicists and medical advisory personnel; it continues this cooperation with Pennsylvania and other contiguous States.

This summary of FDA's action related to the Three Mile Island nuclear accident cannot include details of all the activities undertaken, or the devotion of FDA staff members onsite and at headquarters who served long hours during the crisis in a professional and dedicated manner. Our hope is that it will give the reader insight into FDA's role during the Three Mile Island nuclear accident and provide a guide for what future and continuing FDA activities will be during the clean-up phase of the accident.

MR. GALPIN: I think our time tolerance is growing shorter as the session goes on. Fortunately, Tom has done an excellent job of summarizing some of the overall picture. I will try to make this rather short.

I think a few things are worthy of mention however. The initial EPA notification of the accident was on the 28th. I logged it in at 9:04 a.m.; it came from the NRC operations center. Our general feeling is that considering that NRC headquarters had only been notified somewhere between 7 and 8 a.m., that was a reasonable response and a reasonable notification of us.

On the morning of Thursday, March 29, we had called the Pennsylvania Health Department, and volunteered some analytical support, if they needed it. This was after consultation with NRC to assure ourselves that indeed it probably might be needed. What I gathered from Tom was somehow that information did not get to him personally. That is something you probably ought to look at later.

On Black Friday, a number of things happened. Based on perception of the Administrator of the the Agency, in consultation with, I understand, some high level cabinet members, there was a decision made that indeed an EPA team ought to be sent to the site to perform monitoring. I do not know all that went in to that decision. It was interesting to me that the decision was made in a forum that had never participated in any of the preplanning for emergencies at nuclear power plants in EPA. It surprised us. But I must say, and I think Tom will confirm this, that the team did go in there Saturday and set up about 35 sampling stations in 2 rings. I really have nothing to say, except that it looked to me like they did a creditable job, once that direction was given that something that was going to be done.

I think it does say some things for the future. I think that, as Tom says, regardless of all the papers, be they shiny, glossy, or on rough hewn logs that may be written beforehand, when the time comes that something happens, the perceptions of those that are in positions of authority may well be what rules. Those are what actions are going to be taken upon. We can make some "guestimate" as to what might happen in the future from what happened in the present.

I think you can expect that Federal agencies, with or without the request of a State, are probably going to show up. Several times I had ringing in my ears some of Maggie's statements that she made at many planning sessions, and I had kind of discounted them at the time; they came back to haunt me. She had said, "You know, if we have an accident at a nuclear power plant, one of the biggest jobs we are going to have in the State is handling all of the Feds that are going to be pouring in." I am sure that you had some of those problems.

I do feel, however, that the EPA team that went did a creditable job. I think that the cooperative effort that existed among the Federal agencies and the State's activities in the field, and Maggie confirms this, was a highly commendable operation. I am not talking about the bickering that may have gone on back in the hallowed halls. I am talking about the activities that went on in the field. At 5 p.m. every day, the groups of Feds and State representatives got together, went over all of the monitoring data for that day, made a consolidation, pulled it together, and made a report; something that was reasonable to look at. So I think from that standpoint of what really went on in the field, there was a very commendable cooperative effort there. Others may want to speak to this point when the question period comes.

The EPA monitoring stations that were set up consisted of direct reading, chart recordings; we had instantaneous as well as integration possibility, TLD's, and air samples at each of those stations. EPA did some other things there that I think are worthy of note. One that frankly was not laid on before, and I think was a useful thing to have done was aerial photography, which blown up and placed at the operations center, became a useful tool in looking at the monitoring situation.

Tom already mentioned the water sampling. One of the more recent things that the EPA team had done up there was working with the State in putting in a continuous water monitor at the effluent point. Releases were not happening where they were supposed to be happening. The common mode of analyzing the sample in a tank and then discharging to a liquid effluent and being able to say how much dilution you got, that was not working. One thing that was missing and was installed was a continuous monitor for the water pathway.

At the present time, we still have an EPA team there. They have been charged by the White House with the coordination of the overall monitoring effort that is continuing on through the cleanup phase and the preparation of a report that will go to the President's task force. At one time, apparently also without Tom's knowledge, the Montgomery mobile laboratory had been moved as a backup into the vicinity of Hagerstown, so it was practically in your back yard, Tom. We were told that your office had been informed of this, and I am sorry that word had not gotten to you, either.

One thing had not been mentioned here, and I am going to go ahead and do it, because I am sure that the question is bound to come up. There was a joint task force put together at the headquarters level to look at the assessment of the impact. FDA, EPA, and NRC had all been involved at the NRC operations center on a 24-hour around the clock basis, from at least Friday, the 30th on through the following week. As a part of that activity, as a spinoff from it, they put together an assessment group that developed a rather extensive report that, at least Dr. Mills and I agree, we are going to see gets out on the street as rapidly as possible. This document is about 1/2-inch thick. From this assessment, they indicate that basically using TLD data, they would estimate the highest individual exposure at something less than 100 millirem. In terms of the man-rem, the range of estimates was 1,600 to 5,300 man-rem with a best number selected at 3,300. If you want to use BEIR numbers applied to that, that would indicate something less than one fatal cancer, or up to, at the high range, just about one fatal cancer. It also indicated that the normal population expectancy of fatal cancers over the same time would be about 325,000. So you are talking there about 1 in 325,000. The total number of health effects, including all cancers and genetic effects for all generations, would be somewhere around two such health effects.

I do not think I will say too much more about EPA activities. A couple of lessons; one I have mentioned already, is that there is a handwriting on the wall that Federal agencies might be expected to respond, even though not asked. I know this may give some people some gas. Maybe it is a matter of looking at it as being accepted. If that is to be expected, I do not think there has been an adequate job among the Feds to plan and especially to coordinate. Granted, once we got up there, and had been there a few days, things settled in and the coordination effort occurred. But that was not pre-laid and preplanned, and it should be. If that is going to be the modus operandi of the Feds, then we ought to get together and lay out how we are going to coordiante ourselves, and not depend upon the State having to ride herd on us, but indeed, make it work so that it is going to be a service to the State and supply the data in some consolidated form, rather than be a burden to them.

Many things we have learned, in terms of just the detailed nitty-gritties of planning; advice that had been in our guidance that we see is not going to work; things like suggesting that perhaps hospitals and prisons not be evacuated as a part of an overall evacuation plan; it ain't gonna work. I think we had that in our manual at one time.

Instrumentation; I think we are going to make some recommendations, probably through NRC, in that area. I think, as Tom has already mentioned, probably the number of TLD's that exist around the site ought to be looked at in terms of a permanent grid that ought to be there all the time. Most of the dosimetry information that the risk estimates were taken from were on the basis of that TLD information.

I think with that I will stop.

DISCUSSION

MR. STOCKS: I have, not so much a question, but a comment that it looks to me that almost irreparable damage is done to everybody's rad health program because of the public information. You have all skipped over that. You have got the Naders and the Jane Fondas rubbing their hands with glee on account of this accident and Hendee and what I saw on television and what I heard on the radio, some of it was absolutely appalling. I had to start with NRC, the way it looks to me. I would like to hear just a little discussion of what we, if we had it to do over, could we have stopped this? Could you have stopped these press misinformations?

MR. RYAN: I do not know; I really do not know what you would do in a situation, if we had another one like it. It is, as I said on Sunday night, a supercharged emotional issue. I remember going to the operations center on Saturday morning, the 31th of March (I believe it was Saturday morning). I looked through the paper, I read The New York Times, and I found in section D a piece about a chemical plant which had suffered an explosion in a place called Rahway, New Jersey, in which one worker had been killed and four had been hospitalized. It occupied about 1-1/2 inches of print. The front page of the Times began the piece and it opened into the first section for two full pages of commentary and analysis of what had happened at Three Mile Island. I do not know what the answer is. I think we can say without fear of contradiction that this is a supercharged emotional issue; it is a matter which generated public interest. I cannot blame the press for wanting to cover it. I cannot blame the press for asking pointed questions. I cannot blame the press for analyzing the event in the detail and with the scrutiny that it paid to it. It is the press's right to do that.

It is our duty, as public officials, it seems to me, to answer legitimate questions which come from the press, and if the matter is, in your judgment, played up to excess and it plays into the hands of people that you do not like, I think that there is no response to that. That is tough; that is the way it is.

DR. PARROTT: Tom, something that interested me very much, was that you said that all of a sudden you had a preponderance of communcations gear, which is something that is extremely important to all of us. I have wondered if you could tell us what the source of that gear was, and from there we will take it.

MR. GERUSKY: You have to remember the accident occurred close to Harrisburg. In that area, in that forestry district, there is a good forestry radio network, and that was available to us. If it had happened at another nuclear power plant in Pennsylvania, that system would not have worked, and we would have been in serious trouble with communications. We have to have a communications system that works throughout the State, because there are more than reactor accidents that we have to handle, and we have to communicate with those people anywhere in the State. Radio telephone, in my opinion, will not work. Sorry about that; take your radio telephone out of your car. It may work in Oregon. Maybe people do not use the telephones, but it would not have worked in Harrisburg, and on long distance, it really would not have worked, if we had to make long distance calls across State to contact our people. So radio is the only way, and get a good one.

MR. RYAN: We keep coming back to communications. I do not know if you noticed how many times in the course of the last hour that issue has been raised. In a sense, I think we are lucky at Harrisburg. I do not know what it would have been if we had been in some more remote place with mountains in the way, or with fewer telephone lines, or bother from a large city where you had a lot of trunk lines. I think it is something that, again, we can do something about. The Federal Government has now in its array of agencies, a new agency called FEMA, and I was talking to Karl Seibentritt earlier today, and one of the things that FEMA is talking about is a communications satellite. Again, that is not an outlandish expenditure. A communications satellite would have the ability to hook up all kinds of people in all kinds of emergency situations, whether you are talking about a snow storm or a flood, or a hurricane, or a tornado, or a nuclear reactor accident, or a derailment of a train containing propane. It is a tool which is available. It is something that is tried and true and known and tested and it seems to me that it is the wave of the future, and we have to get something like that.

MS. HAARS: This is a comment to the Federal agencies, and particularly to you, Bob Ryan, since you have lead agency for concurrence of plans. I would like to request that assistance from the Feds in an emergency response be flexible. It appears to me at times that it has to be one way, and the most important thing is that a State plan works when it needs to.

MR. RYAN: I agree. The State plan is a piece of paper, unless it works. Somebody said a glossy, plastic covered plan is not much good intrinsically, and that is true. It is only good if it works in practice. As to flexibility, I think I agree with you. We have to be flexible in these things to meet the peculiar circumstances of the situation in which we find ourselves. I like to think that we built some flexibility into the concurrence process, by virtue of the fact that we open up that list of essential elements for scrutiny, not only by Feds, but by State agencies periodically. We are in abeyance on the 70 elements right now, pending some kind of a resolution of the NRC/EPA task force recommendations. When that is in hand, up or down, probably in the next couple of months, we will be in a position to hear and to field suggestions for changes in that list of essential elements and for interpretation of those necessary elements. We have already had a number of comments from a number of State agencies about them, and a number of comments from Federal agencies about them, particularly from the Department of Transportation, which is very interested in bringing in a number of transportation related elements as essential.

MR. HARDIN: With all the people running around, Tom, collecting data, I was glad to hear that at 5:00 every evening you would get together and try to discuss this. NRC was collecting data, and FDA was collecting data; were they involved in that discussion (MR. GERUSKY: Yes), and when there were some possible differences of information, how were they resolved?

MR. GERUSKY: There were very few. There were a couple of serious ones. They were resolved at the 5 o'clock meeting; they were resolved before the 5 o'clock meeting, by having someone else run the sampling--do the sample evaluation, and came up with a number that was agreed to by all. There were some problems and some slipped numbers; off by a factor of 60, and so forth (kept me awake one Easter Sunday night, worrying about iodine-131 that was not there in the quantities that was predicted). You know, one of the things that Maggie mentioned, and one of the things that happened, was that there was fatigue all across the board. It was not just our staff that got tired; everybody got tired. People who had been working a 12-hour shift for 14 days and had not had a chance to get away get tired and they are not as sharp as they were when they first came on board. So that is another thing that has to be looked at; make sure you have adequate turnover of personnel so that there is adequate rest for the people. We did not have any serious problems with data, except for one that I can remember. There were some problems.

There was one problem that was rather interesting. The site does not have a sewage treatment plant. They took a sample of the sewage that they wanted to take offsite, and found "cesium-137" in it. We would not allow them to take it offsite. We told them how to store it onsite so that it would not blow up. After about a week, they decided to analyze it again, and did not find anything. Our water people were concerned about stuff leaving the site without having it adequately checked. At one point, somebody had a local police department stop a sewage truck in the street, so somebody could go up and check it with a GM counter to see it it was radioactive or not. There were some funny episodes; we just could not believe that that would happen. I guess we were responsible, because we told them if there was anything really bad, you could find it with a Geiger counter.

Most of the time the numbers came out; the people who were doing the counting knew how to do it. Except for rare instances, there were no problems.

DR. SOLON: On the basis of this experience, in your collective or individual view, would the stockpiling of the therapeutic blocking doses of potassium iodide as a public health measure by local jurisdictions be indicated in areas that are in reasonable proximity to reactors?

MR. GERUSKY: Yes.

MR. RYAN: Yes.

DR. SHLEIEN: I think so.

MR. GALPIN: I think some should be available in the reasonable vicinity.

DR. SHLEIEN: Just a comment on the discussion and that question to some extent. I mentioned it earlier, but would like to reemphasize that there is currently in the FEDERAL REGISTER that guidance in draft form. I think that this is an opportunity for the States to have a real input and a real impact on what is going on. I think that this was not the case in the past. The other thing is that the use of KI adds an element of flexibility. Even if there are Federal guidelines available, they should be flexible enough that the State can work within them. Furthermore, a guideline should not voilate the State's use of the principles of good health physics.

DR. PARROTT: In our comments of stockpiling the iodine and things like that are kind of interesting, because our evacuation plans call for removal of all persons in the area who would receive over the lifetime of the incident or accident (whatever you call it) a level of 5 rem thyroid dose. So consequently, this is considerably below the action level that we would even administer potasium iodide; so why the potassium iodide; is there an answer to that?

MR. GALPIN: I think one thing, and something to be included in the manual (Bernie can speak to this, too), is that not everybody is going to be evacuated. You are going to have some emergency workers there, whether keeping the place from burning down, or whatever the case may be. You have got two options with those people in terms of a protective action; you can either mask them or you can block their thyroids, or you can do both. So there is that consideration; not everybody is going to be leaving that area probably at the limits that you are talking about, Marshall.

DR. PARROTT: I do not have a problem with emergency personnel. This, I am in complete agreement would be immediately available from the site, for example, which is where stockpiling would occur for emergency personnel--the site and in the county emergency services department--because, indeed, we should have that. But, with that kind of thinking, and then talking broadly constantly, are you really saying all of the people. You know, stockpile in a bunch of locations. It makes me kind of nervous to think that maybe I should have that stockpile, but yet I am going to move all these people out, with the exception of the emergency people.

DR. SHLEIEN: I think you have hit on an important question. Again I emphasize the use of KI adds a possibility of flexibility to other options. I think in certain situations, you would like to have it available as an option. I think one would have to seriously consider how much you want to stockpile, where you want to stockpile, and the costs involved. I think it is a good idea that has to be thought through carefully. Having KI available, permits one to have another option, and that is, I think, a worthwhile thing.

MR. CASHMAN: Tom, I think it was well what you brought on your communications; you were able to use existing equipment that was in another organization. It is always important to know what is available., until you are able to upgrade what you need to take care of a future incident. You sort of downplayed your only having four TLD's, but they were also serving a useful function; they were there at the time the incident started. You had some crosscheck with the utilities and had a little bit more confidence in them, so I think that is important. Obviously, we all need to look at upgrading what we have around. The question gets into what you feel is sort of a minimum requirement to give you the guidance for making a decision on what is the actual level in the environment. If you have TLD's and so forth, it takes time to go out and get them back. If that initial pressure surge inside containment had actually caused a tour--3 percent leak--TLD's were not going to help you. You have mentioned ERAC; would that be tied into a State center? In addition to ERAC, what would the State of Pennsylvania recommend for at measurement techniques around the reactor?

MR. GERUSKY: I do not even think you would use measurement techniques. You would use wind speed and source term, and get the people the hell out of there as fast as you could, and then verify it later that you did not go in the wrong place. We knew that there was negative pressure in the containment when we asked them to go check that it was not an oversurge of pressure in the containment. I do not think we would have taken even that option; we would have said go, if there had been high pressure in the containment. I think that you cannot rely upon offsite measurements to make decisions. You can use them as a backup tool, but not to make decisions.

MR. CASHMAN: I will rephrase the question a little bit. There was a great deal of concern that the utility did not give early information to the State; that they may have had a problem. Now they did not have significant offsite release, but there was some onsite release, apparently.

MR. GERUSKY: I do not think they realized that there was offsite release.

MR. CASHMAN: Do you have any suggestions as to how the State could have an independent check so that you did not have to rely upon them?

MR. GERUSKY: It has been suggested in a couple of bills that have been introduced in our legislature that all of the monitoring equipment be immediately able to be read out at the location of the monitor. In informing the legislature that that is an impossibility, they said so what, they still want it in the legislation. There are some that can provide that kind of information. We are talking about a million dollar program around one plant, if you really go to that extreme. I do not want this accident to cause us to have to spend money that is not needed. I would like another hard look at the whole thing. I think we have to spend more money, but the question is, how much and in what manner. I do not think we ought to rush into any particular program. We will take a long hard look at what we are doing, and how it can be improved, and not just go out and buy, buy, buy.

CLOSING

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MR. LACKER: We are now in the closing session of this Eleventh Annual Conference of the Radiation Control Program Directors. At the close of this meeting, we begin a new year of conference activity, endeavors, and pursuits. At this meeting, we have looked at radiation exposure levels--how low should we and can we go with those limits. I think it has been a good meeting, an informative meeting, and a fun meeting.

I would like to express, on behalf of the Conference, our deep gratitude to Dale McHard, Bob Craig and the other members of the Oklahoma Radiation Control staff for hosting us at this meeting and the excellent way that the meeting proceeded. Until you have hosted one of these meetings, there is no way you can understand the load that is on those people.

I would also like to express my personal appreciation to Alice Dolezal for her leadership during the last year. Certainly her leadership has made my job this coming year a much easier one. She has gotten the organization going well and all I will need to do is maintain that momentum that she has established.

Last but certainly far from least, those ladies who worked so hard in performing the clerical duties that were necessary during this Conference, the registration desk and the central office, seeing that the copies that we needed were made, the typing that was needed was done, answering your questions about where things were and what was going on; certainly they deserve our appreciation.

As most of you know, the activities and endeavors of our Conference are supported basically by four Federal agencies at this time; BRH, EPA, NRC, and NBS. Because most of us understand what those letters mean, I am not going to use the long titles.

This is the last session; we have taken a lot of important steps in the growth of the Conference at this meeting. We have decided that the next step in the maturing of our organization is to have a full-time paid executive secretary and the Board will be working on this for the next year. We have decided that there are needs for some additional task force work so we will be calling on you for those things. I appreciate very much the fact that this group is a cooperative group and we are always ready to do the job that is to be done.

As suggested by the keynote speaker, Dr. Norm Hillberry, "...that we continue to pursue the resolution of difficult problems for the benefit of the general public through the combination of technical and social exchange between the States, or Federal allies (I hope), suppliers, and users."

MR. SCHWARTZ: At the opening session of the Conference, we heard statements about clout and maintaining clout for the Conference. We talked about truth telling; we talked about educating the public, and public confidence in the bureaucracy. These are specific areas that all of us must work on and I submit that these are our challenges. Are we prepared to meet them? I will say yes, and I will try to explain in a very short time, why.

I personally find exciting, and I am proud to be involved in the growth of the Conference over the last few years. Dave mentioned already a few of the highlights. The incorporation of the Conference was a major step in the growth of the Conference because I believe it gave the States a rallying point, a single voice, and I believe a very strong voice. The professional clout of the Conference on technical issues is greater than any individual State or group of States. At this meeting here in Oklahoma City you have taken another giant step--the decision to hire a full-time executive secretary to cope with the increasing focus on radiation on a day-to-day basis. It seems that organizationally you are prepared to take the lead nationally and perhaps internationally in identifying issues and recommending solutions. I submit that this may not be an easy position to maintain. Professional clout is not given, it is earned. It is earned through a sustained demonstration of professionalism, through confident, mutual respect and openness.

We as regulators, and I mean we, are mandated to operate in this manner, in an open, professional manner with mutual respect for each other. I think we must do that if we are to maintain the public trust. The challenges are there before us. I think that through the years we have developed the spirit of cooperation and partnership between the States and the Federal government. I admit that these are sometimes only words, and we all need to work hard to assure that their meaning is not lost.

I believe that the Conference is alive, it is a dynamic organization, and I do have the confidence that together we can face the challenges over the coming year.

I want to congratulate Alice Dolezal, your able chairwoman for the last year. She has taken the Conference through a very difficult year and kept things working. To Dave Lacker, your new Chairman, I pledge my support and that of my agency, to the programs he has outlined for the future. I want to congratulate Marshall Parrott, your Chairman-Elect, who I will be working with on the Board. Again I would like to echo my personal thanks to Dale and Mary McHard and their children, and to Bob and Esther Craig and their children, and the staff of the Oklahoma Program who really made this a great meeting.

DR. AUGUSTINE: I think we owe a lot of thanks to the participants in the technical sessions as well as those of the State Program and others who worked so hard to make this Eleventh Annual National Conference a success. Your chairwoman, past chairwoman now, Alice Dolezal in her opening remarks suggested that we are beginning to reap some of the fruits that we have been sowing and working on in the past years; these efforts to achieve control of radiation in an effective and efficient manner and the theme of our Conference this year, Minimizing Exposure; Optimizing Use.

Unfortunately I think some of the fruits that we are reaping are kind of bitter. We have the fruits of the loss of credibility of scientists and the loss of credibility of official agencies at all levels of government. These agencies are part of the so-called establishment and I believe the establishment was established for the purpose of providing a credible source of information and for the purpose of protecting the health and welfare of the people. There is alledgedly a general feeling of distrust for the establishment and I say alledgedly because I really think the majority of the public still trusts in the establishment and specifically in the radiation control agencies which are part of the big establishment. Notwithstanding any of the little, if I may quote "Tom screwups or Maggie screwups" that did occur at Three Mile Island. I may be biased as I think most of us sitting in the room are, but I am somewhat proud of the radiation control agencies in the establishment, screwups notwithstanding, and proud of these radiation control agencies at all levels of government.

I really believe that we are credible. I think the problem may be to get the message across to the nonbelievers or to those who have never heard our message, perhaps because we don't speak clearly enough for them to understand us or we don't speak loud enough to be heard above the babble of those who preach the evils of radiation and the evils of nuclear power and the evils of the "establishment." You have already heard that Tom Gerusky is an evil man. I found Dr. Hilberry's presentation somewhat thought provoking. I think a lot of things he said we said to ourselves, "gee, that's right; why haven't we thought of that?"

I would like to bring up a few of the points that he had mentioned to reemphasize them here. First of all he said that we have a people problem in radiation, not a technical problem. I think we all agree with that, especially after Three Mile Island. He said we need to be sure to tell the public our story, but not only the public but also the other disciplines. There are other people we have to educate, there are other parts of our bureaucracy and our establishment that we have to educate, usually it is in the upper direction. We have to understand the mood of the public, and tailor our approach to fit this particular mood. That the public's attitude or feeling depends not on the facts but on their perception of the facts is a very important point. That again I think was really exemplified in the Three Mile Island incident. And finally, in order to get our message across to the public, we need to first meet the media's needs in order to have the media meet our needs. Again I think Three Mile Island was a good example. The media had a need, they had to have news, they had to have something that people wanted to read and I think they perhaps sometimes even generated what they thought people would like to read because we were not meeting their needs of giving them something they could grasp ahold of and run with.

As Dr. Bill Mills indicated in his remarks, I believe it is time that we in the radiation control establishment, at each of our government levels, stand up and be heard and be counted. We must present the facts in a manner that is understandable, we must present them so that they can be perceived correctly and we must speak loud enough to be heard by the media and by the public. I think we must be more definitive in what we say and we must also be able to say what we do not know. Finally, I think we have to be able to go with what we consider our best judgment and very often the problem is that we fail to reach that final step of making our best judgment and going ahead and taking action. I really think the public wants to hear our best judgment. I think they trust our best judgment and I think they will find it is credible if we can get this message across too. On behalf of the Environmental Protection Agency, the people here and the other people back home, I do want to thank the Conference, the past chairmans, the current chairmans, the chairman elect and the other Conference officers, elected members, for this opportunity of continuing our cooperative efforts in this Federal-State relationship.

DR. MILLER: I consider it a real honor and a privilege to have the opportunity to say a few words at the conclusion of our annual meeting. As many of you know I feel a great sense of pride in regard to this Conference, something akin to being a Godfather. I have watched you grow over the last 11 years into a cohesive and productive organization, one that is recognized for its expertise and effectiveness in working with your Federal counterparts, or liaison people if you so desire, which isn't always easy. I would like to add my special thanks to those of Dave, Bob, Shelley, to all of you who have attended and contributed to the continued success and excellence of our annual meeting. It has become a challenge to make each year better than the last and we have succeeded once again. But it only happens as the result of your interest, dedication, concern, and participation.

Every organization can be divided into about three groups, those who make things happen, those who watch things happen, and those who wonder what happened. Your organization is no exception but thank goodness you have many people in your organization who want to make things happen. One of those is your host and past chairman, who has worked hard for the Conference over the years, and his presence will be missed on the Board. I am certain that he will continue to stay involved and give us his guidance. So thank you Dale for the contribution to the progress of the Conference and the success of this meeting, it could not have happened without you and your staff. I know it is a lot of hard work, I have done it for many, many years, and as Dave said, only those who have done it can appreciate it.

Before closing, I would like to express my appreciation to Miss Alice for the superb job she has done as your Chairman. I don't think enough has really been said about the fine work she has done all year. She is really a take-charge woman as you have noticed this afternoon. She has done a tremendous job, it has been a pleasure working with you and I am glad you are staying on as floor manager.

I also want to welcome Marshall Parrott; you know he has been on the Board before and made so many contributions and gave such good advice on the Board that they would invite him back to serve as chairman. Congratulations, Marshall.

It has been a great meeting. I appreciate you all coming and I hope you will all come to Louisville, we are going to have another super program for you and I will look forward to seeing you then. So on behalf of the Food and Drug Administration, especially the Office of the Commissioner, the Bureau of Radiological Health, and EDRO, I want to compliment you all for your contribution to this delightful, informative, and productive 11th Annual Meeting.

*U.S. GOVERNMENT PRINTING OFFICE: 1981-0-341-177/46

FDA 80-8126	Symposium on Biological Effects, Imaging Techniques, and Dosimetry of Ionizing Radiations (July 1980) (GPO 017-015-00175-0, $8.00) (PB 81-112351, mf only).
FDA 80-8128	The Selection of Patients for X-ray Examinations: The Pelvimetry Examination (GPO 017-015-00174-1, $2.00) (PB 81-113490, mf only).
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FDA 80-8130	Nationwide Survey of Cobalt-60 Teletherapy: Final Report (PB 81-101784, $9.50).
FDA 80-8131	Vignettes of Early Radiation Workers: A Videotape Series (flyer).
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FDA 81-8027	Directory of Personnel Responsible for Radiological Health Programs (supersedes FDA 80-8027, March 1980).
FDA 81-8033	Bureau of Radiological Health Publications Index (supersedes FDA79-8033) (PB 81-156192, $18.50).
FDA 81-8034	Report of State and Local Radiological Health Programs, Fiscal Year 1979 (PB 81-167678, $6.50).
FDA 81-8042	CSU-FDA Collaborative Radiological Health Laboratory Annual Report 1979 (PB 81-184566, $15.50).
FDA 81-8070	Bureau of Radiological Health Publications Subject Index (supersedes FDA 80-8070, May 1980) (PB 81-149478, $5.00).
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FDA 81-8162	Handbook of Computed Tomography -X-Ray Spectra (PB 81-295890, $11.00).
FDA 81-8164	Calculation Programs for Routine Compliance Testing of Diagnostic X-Ray Systems (PB 81-200503, $8.00).